

1 **UNITED STATES DISTRICT COURT**
2 **FOR THE DISTRICT OF NEW JERSEY**

3 **IN RE: VALSARTAN, LOSARTAN, CIVIL ACTION NUMBER:**
4 **and IRBESARTAN PRODUCTS 1:19-md-02875-RMB-SAK**
5 **LIABILITY LITIGATION Case Management Conference/**
6 **Daubert Hearing**

7 Mitchell H. Cohen Building & U.S. Courthouse
8 4th and Cooper Streets
9 Camden, New Jersey 08101
10 Monday, September 9, 2024
11 Commencing at 10:13 a.m.

12 **B E F O R E:** **THE HONORABLE RENÉE MARIE BUMB, CHIEF**
13 **UNITED STATES DISTRICT JUDGE, and**
14 **THOMAS I. VANASKIE (RET.), SPECIAL MASTER**

15 **A P P E A R A N C E S:**

16 HONIK LLC
17 BY: RUBEN HONIK, ESQUIRE
18 DAVID J. STANOCH, ESQUIRE
19 1515 Market Street, Suite 1100
20 Philadelphia, Pennsylvania 19102
21 Co-Lead Counsel for MDL Plaintiffs

22 MAZIE SLATER KATZ & FREEMAN, LLC
23 BY: ADAM M. SLATER, ESQUIRE
24 CHRISTOPHER J. GEDDIS, ESQUIRE
25 103 Eisenhower Parkway, Suite 207
26 Roseland, New Jersey 07068
27 Co-Lead Counsel for MDL Plaintiffs

28 KANNER & WHITELEY, LLC
29 BY: CONLEE S. WHITELEY, ESQUIRE
30 701 Camp Street
31 New Orleans, Louisiana 70130
32 Co-Lead Class Counsel for Third-Party Payor Economic Loss

33 John J. Kurz, Official Court Reporter
34 John_Kurz@njdc.uscourts.gov
35 (856) 576-7094

36 Proceedings recorded by mechanical stenography; transcript
37 produced by computer-aided transcription.

A P P E A R A N C E S: (Continued)

NIGH GOLDENBERG RASO & VAUGHN, PLLC
BY: C. BRETT VAUGHN
14 Ridge Square NW, Third Floor
Washington, D.C. 20016
Co-Lead Class Counsel for Third-Party Payor Economic Loss

RUEB STOLLER DANIEL, LLP
BY: BEHRAM V. PAREKH, ESQUIRE
515 S. Figueroa Street, Suite 1550
Los Angeles, California 90071
Counsel for Plaintiffs' Executive Committee and all Plaintiffs

SLACK & DAVIS LLP
BY: JOHN RANDOLPH DAVIS, ESQUIRE
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Counsel for Plaintiffs

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
BY: JESSICA DAVIDSON, ESQUIRE
ALLISON M. BROWN, ESQUIRE
JOSEPH CARUSO, ESQUIRE
JORDAN EINSTEIN, ESQUIRE
One Manhattan West, Suites 42-128
New York, New York 10001
Counsel for Defendants Zhejiang Huahai Pharmaceutical Co.,
Ltd., Huahai U.S., Inc., Princeton Pharmaceutical, Inc., and
Solco Healthcare U.S., LLC (collectively ZHP)

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
BY: NINA R. ROSE, ESQUIRE
1440 New York Avenue, N.W.
Washington, D.C. 20005
Counsel for Defendants Zhejiang Huahai Pharmaceutical Co.,
Ltd., Huahai U.S., Inc., Princeton Pharmaceutical, Inc., and
Solco Healthcare U.S., LLC (collectively ZHP)

KIRKLAND & ELLIS LLP
BY: DEVORA W. ALLON, P.C.
ALEXIA R. BRANCATO, ESQUIRE
601 Lexington Avenue
New York, New York 10022
Counsel for Defendants Torrent Pharma, Inc. and
Torrent Pharmaceuticals Ltd. (collectively Torrent)

(Appearances continued onto next page)

A P P E A R A N C E S: (Continued)

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI LLP
BY: CLEM C. TRISCHLER, ESQUIRE
JASON M. REEFER, ESQUIRE
One Oxford Centre, 38th Floor
Pittsburgh, Pennsylvania 15219
Counsel for Defendant Mylan Pharmaceuticals, Inc.

GREENBERG TRAURIG LLP
BY: VICTORIA DAVIS LOCKARD, ESQUIRE
3333 Piedmont Road, NE, Suite 2500
Atlanta, Georgia 30305
Counsel For Defendants Teva Pharmaceutical Industries Ltd.,
Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma,
Inc. (collectively Teva)

GREENBERG TRAURIG LLP
BY: GREGORY E. OSTFELD, ESQUIRE
77 West Wacker Drive, Suite 3100
Chicago, Illinois 60601
Counsel For Defendants Teva Pharmaceutical Industries Ltd.,
Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma,
Inc. (collectively Teva)

WALSH PIZZI O'REILLY FALANGA LLP
BY: LIZA M. WALSH, ESQUIRE
Three Gateway Center, 100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
Counsel for Defendant Teva

ARCHER & GREINER, P.C.
BY: MAUREEN THERESA COGLAN, ESQUIRE
1025 Laurel Oak Road
Voorhees, NJ 08043
Counsel for the Mylan defendants

CROWELL & MORING LLP
BY: ANDREW KAPLAN, ESQUIRE
1001 Pennsylvania Avenue, NW
Washington, DC 20004
Counsel for Defendant Cardinal Health

BARNES & THORNBURG, LLP
BY: KARA KAPKE, ESQUIRE
11 South Meridian Street
Indianapolis, IN 46204
Counsel for Retailer Defendants and CVS Pharmacy, Inc., and
Walmart, Walgreens

A P P E A R A N C E S: (Continued)

FALKENBERG IVES LLP
BY: KIRSTIN B. IVES, ESQUIRE
230 W Monroe Street, Suite 2220
Chicago, Illinois 60606
Counsel for Defendant Humana

NORTON ROSE FULBRIGHT US LLP
BY: D'LESLI DAVIS, ESQUIRE
2200 Ross Avenue
Suite 3600
Dallas, Texas 75201
Counsel for Defendant Mckesson Corp.

Also present:

Arthur Roney, The Courtroom Deputy

Loretta Smith, Esquire, Judicial Law Clerk to the Honorable
Robert B. Kugler (Ret.)

Terry Henry, Esquire, Camber, Hetero

Douglas Tween, Esquire, representing VivaMed

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1 (PROCEEDINGS held in open court before the Honorable
2 Renée Marie Bumb, Chief United States District Judge, and
3 Thomas I. Vanaskie (Ret.), Special Master, at 10:13 a.m. as
4 follows:)

5 THE COURTROOM DEPUTY: All rise.

6 CHIEF JUDGE BUMB: Good morning.

7 MR. SLATER: Good morning, Your Honor.

8 MS. ALLON: Good morning, Your Honor.

9 MR. HONIK: Good morning, Your Honor.

10 MS. BRANCATO: Good morning, Your Honor.

11 ALL COUNSEL: Good morning.

12 CHIEF JUDGE BUMB: Good to see you all. You can all
13 have a seat. Happy end of summer.

14 All right. Let me just -- well, I was going to start
15 with appearances.

16 Okay. We're here, the case is the *In Re Valsartan*
17 matter. The docket is 19-2875. So I'm going to start with the
18 appearances. We'll start with the plaintiffs.

19 MR. SLATER: Good morning, Your Honor. Adam Slater
20 and Chris Geddis here for plaintiffs.

21 CHIEF JUDGE BUMB: Okay. Good morning.

22 MR. HONIK: Good morning, Your Honor. Ruben Honik.

23 CHIEF JUDGE BUMB: Good morning.

24 MS. WHITELEY: Good morning, Your Honor. Conlee
25 Whiteley on behalf of plaintiffs.

1 CHIEF JUDGE BUMB: Good morning.

2 MS. ALLON: Good morning, Your Honor. Devora Allon
3 from Kirkland & Ellis for Torrent.

4 CHIEF JUDGE BUMB: Good morning.

5 MS. BRANCATO: Good morning, Your Honor. Alexia
6 Brancato from Kirkland & Ellis, also for Torrent.

7 CHIEF JUDGE BUMB: Good morning.

8 MR. OSTFELD: Good morning, Your Honor. Greg Ostfeld
9 for Teva.

10 CHIEF JUDGE BUMB: Good morning.

11 MS. LOCKARD: Victoria Lockard, Greenberg Traurig,
12 for Teva.

13 CHIEF JUDGE BUMB: Good morning.

14 MS. DAVIDSON: Good morning, Your Honor. Jessica
15 Davidson, Skadden Arps, for ZHP.

16 CHIEF JUDGE BUMB: Good morning.

17 MS. BROWN: Good morning, Your Honor. Alli Brown,
18 also from Skadden, for ZHP.

19 CHIEF JUDGE BUMB: Good morning.

20 MS. ROSE: Good morning. Nina Rose, also from
21 Skadden, for ZHP.

22 CHIEF JUDGE BUMB: Okay. Good morning.

23 Anybody else want to enter an appearance?

24 (No response.)

25 CHIEF JUDGE BUMB: No? Okay.

1 So I set this down. Thank you for your case
2 management -- I want to acknowledge Judge Vanaskie is with me
3 today. Always so happy that he is here with us.

4 So I've received the case management conference
5 letters. I want to go through as many of the issues, hopefully
6 all of them, that I can. But I thought that I would start with
7 the testimony of Expert Conti because I want to resolve that
8 issue.

9 But before I do that, I really want the parties to
10 talk to me about -- it seems to me the parties, which I'm not
11 understanding why there is such a disconnect. But it seems to
12 be a disconnect between the plaintiffs' theory of the case in
13 terms of damages. And this is how I'm just going to frame it,
14 and then I'm going to have the parties respond.

15 So there are separate theories of economic loss,
16 benefit-of-the-bargain, which, generally speaking, discusses
17 that the measure of damages is the difference in the value of
18 what was bargained for versus what was received; and then the
19 defendants say there's an alternative product theory, a
20 quantity effect theory, which says that the damages are that
21 one can recover the entire amount if they prove -- if in this
22 case the plaintiffs prove that their members would not have
23 been prescribed any other drug. So it's sort of in the
24 "but-for world."

25 The defendants say, well, the plaintiffs' theory of

1 damages is sort of in the middle of both.

2 Mr. Slater, I guess I'll turn to you. It seems to me
3 your measure of damages that you're pursuing is the benefit of
4 the bargain. Plaintiffs got nothing. They had no value.

5 Am I right?

6 MR. SLATER: That's correct.

7 CHIEF JUDGE BUMB: And so in doing that, you then
8 concede that the defendants should be permitted to present
9 evidence that they did have value.

10 MR. SLATER: Well, obviously, this has been heavily
11 argued and briefed, and I'm going to hand off to Ruben Honik in
12 a moment. I'll just say briefly, we think that there's reasons
13 they shouldn't because of the adulteration issues.

14 CHIEF JUDGE BUMB: Help me understand that.

15 MR. SLATER: Because the drugs had no -- they did not
16 have a legal right to sell those drugs because they were
17 adulterated, because they had NDMA and NDEA in them, which was
18 not approved and which was a basis for adulteration for the
19 reasons that Your Honor is aware of.

20 So that's the argument that we make, that they
21 shouldn't be allowed to. Because this whole but-for world, it
22 didn't exist. And since it's a warranty case and really the
23 consumer fraud claims run the same theories basically, what was
24 sold did not have value. And you don't look to what would have
25 happened in a but-for world, because in that case, as we've

1 argued, you would end up with no damages in any case where you
2 actually would have bought a different -- like if you bought a
3 car and you got the warranty. They would say, well, you needed
4 a car anyway, so you didn't really lose the benefit. But, no,
5 you recovered the cost of the car.

6 I'll hand it off to Mr. Honik if he wants to put a
7 finer point on it.

8 CHIEF JUDGE BUMB: Yeah. Okay. We need to really
9 flesh this out because --

10 MR. HONIK: If Your Honor, please.

11 CHIEF JUDGE BUMB: Yeah.

12 MR. HONIK: If I may answer your question directly.
13 In a theoretical world, the defendants should be permitted, in
14 some form or fashion, to present expert testimony about the
15 value of this drug and under whatever theory they can advance.

16 The problem -- and we have briefed this -- is that
17 none of their experts have done that. They have not arrived at
18 a model, a formula, a method, or a calculation of any sort that
19 demonstrates value associated with this drug. They've largely
20 spent their entire breath in attacking the model that we have.
21 And of course, Judge Kugler, on no fewer than I think three or
22 four occasions, said it is a perfectly sound economic model
23 that the jury can consider.

24 CHIEF JUDGE BUMB: Are you saying to me that Judge
25 Kugler ruled unequivocally, defendants, go ahead, retain your

1 experts, your experts will be permitted to testify that these
2 drugs did what they were supposed to do, they lowered the blood
3 pressure, and you can present evidence? Did Judge Kugler
4 unequivocally rule that?

5 MR. HONIK: He didn't rule that. What he did rule,
6 as I read his writing in this case, is that the damages are
7 somewhere between zero and the full value, conceptually, and
8 that defendants may have experts that address where on that
9 continuum the damages lie.

10 What we've done, because we've now had the benefit of
11 seeing and reading their expert reports, is to file motions in
12 limine to preclude their testimony on this subject, because
13 they have failed to meet the requirements of 702 and present
14 any demonstrable, reliable method for arriving at what the
15 value could be.

16 CHIEF JUDGE BUMB: So you -- it sounds like you and
17 Mr. Slater are saying two different things.

18 Mr. Slater is saying to me it doesn't matter if they
19 had therapeutic value. They couldn't have sold them to begin
20 with because they were deemed adulterated.

21 You seem to be saying that the defendants had an
22 opportunity to show that they had therapeutic value, but under
23 Rule 702, their experts fall.

24 MR. HONIK: I think --

25 CHIEF JUDGE BUMB: Those seem to be two different

1 things you're saying to me.

2 MR. HONIK: They're not. I believe that they can be
3 held in two hands at the same time. We believe in our economic
4 model.

5 CHIEF JUDGE BUMB: Yeah.

6 MR. HONIK: The fact that this is a
7 benefit-of-the-bargain case without question and that the point
8 of sale is where that transaction, economically speaking, has
9 been complete -- is complete, we know that the price at that
10 point in time is what the damages are. And in its simplest
11 way, Professor Conti has taken the price from reliable data
12 times a quantity and said those are the damages that we've
13 suffered.

14 CHIEF JUDGE BUMB: Okay. That --

15 MR. HONIK: And that flows from what Mr. Slater said,
16 because this is a benefit-of-the-bargain calculus.

17 All I'm adding is that Judge Kugler, for however one
18 might view it, has ruled that the actual measure is somewhere
19 between zero and the full value that we claim, and I don't know
20 that there has been a ruling specifically precluding the
21 defendants from trying to establish that. All I'm conveying at
22 the same time, that this is a benefit-of-the-bargain case, is
23 that they failed to do that.

24 CHIEF JUDGE BUMB: So you are agreeing then that --
25 your theory is the benefit-of-the-bargain. You are agreeing

1 that the issue for the jury to decide is did these drugs have
2 zero value? Yes or no. Or the defendants say that they had
3 some value, they had some therapeutic value.

4 You believe that that issue can be squared up and put
5 to the jury, right?

6 MR. HONIK: I believe that the issue should be
7 decided as a matter of law by Your Honor in precluding the
8 defendants from attempting to show that.

9 CHIEF JUDGE BUMB: Why?

10 MR. HONIK: Because they don't have an expert.

11 CHIEF JUDGE BUMB: That's a different issue. Because
12 then the question I'm going to ask is, and this is what I'm
13 concerned about, do they not have an expert because of some
14 prior ruling that prevented them from doing it? I'm just
15 trying to square this all out.

16 It seems to me that if the plaintiffs' theory is the
17 benefit-of-the-bargain, then the plaintiffs present evidence to
18 the jury that these drugs had no value, okay.

19 The way I look at it is this: Let's just assume
20 hypothetically that what the defendants sold were placebos,
21 sugar pills, whatever you want to call them. The question
22 then, under the benefit-of-the-bargain theory is, the jury is
23 then asked did they have any value? There wouldn't be any
24 dispute. They had no value. How could the defendants in good
25 faith argue that they had any value? They were sugar pills.

1 Okay. Here the jury is being asked did the
2 defendants -- did the plaintiffs pay for something that didn't
3 have any value?

4 The defendants, it seems to me, should be permitted
5 to present evidence that there was a therapeutic value, that
6 they did, in fact, lower blood pressure. If their experts have
7 failed to do that, then that's on them. Then they have no
8 evidence to present to the jury.

9 If, however, they've been perhaps precluded from
10 presenting that evidence, then I would want to hear more about
11 that, but it sounds to me you're agreeing with me that that is
12 an issue that goes before the jury. Plaintiffs say no value;
13 defendants say value. Jury, you decide.

14 How a jury decides this -- and this is going to be,
15 you know, some bells are going to go off -- without the issue
16 of causation is concerning to me.

17 MR. HONIK: Judge, let me respond to you this way.

18 CHIEF JUDGE BUMB: Yes.

19 MR. HONIK: If Dr. Conti on our behalf wrote an
20 exemplary report that said, without more, the drugs have no
21 value because they could not be legally placed into the market
22 by reason of the FDA regulations, which is a true statement,
23 and stopped there and didn't quantify that proposition, there's
24 no question that under 702 she wouldn't be permitted to get
25 onto the stand and present that and invite the jury to

1 speculate on what those damages are.

2 CHIEF JUDGE BUMB: But those aren't the facts.

3 MR. HONIK: If I may.

4 CHIEF JUDGE BUMB: Well, I know, but --

5 MR. HONIK: But that's what the defendants have done
6 through Dr. Stiroh. Dr. Stiroh has said the drugs have some
7 value because therapeutically that's a true proposition, and,
8 in fact, Professor Conti agrees.

9 What Judge Kugler, quite wisely, noted is that
10 therapeutic or clinical value has no place in the economic
11 damage model that we've prepared, full stop.

12 Having said that and I'm not sure --

13 CHIEF JUDGE BUMB: Explain that to me. Explain that
14 to me.

15 MR. HONIK: Well, what I was looking for is the
16 Judge's actual language, which I think can state it far better
17 than I possibly can.

18 CHIEF JUDGE BUMB: In the summary judgment?

19 MR. HONIK: It appears in a couple different places.

20 CHIEF JUDGE BUMB: Because I read through his summary
21 judgment ruling, and he seems -- the way I read the summary
22 judgment ruling is the jury will decide whether they were
23 worthless or not, which says to me that the plaintiffs get up
24 and they present their case, they say these drugs were
25 worthless, zero value, the defendants get up and say, well,

1 there was some value to them.

2 MR. HONIK: And 702 should preclude anybody, whether
3 the defendants or us, if we were to take this position, from
4 saying they have some value without demonstrating a methodology
5 to calculate it.

6 We can't have the jury speculate on what that value
7 is and then use it as an offset.

8 CHIEF JUDGE BUMB: And that I agree with. That's a
9 702 issue. But I think we're saying the same thing, but you
10 don't think we are. I think we're saying the same thing, which
11 is it is up to the jury to determine whether or not these drugs
12 had value. No, they didn't, and the defendants can then
13 present evidence that they had some value. How they do that is
14 an issue under 702. I get that.

15 But you can't present evidence that they should never
16 have been sold in the first place because that's -- that's not
17 what the facts are. I mean, it wasn't determined that they
18 were adulterated until later on, but then -- well, I suppose
19 you could, but then you could make that argument.

20 But by the same token, the plaintiffs can then say,
21 well, okay, yeah, they shouldn't have been sold because they
22 did have the contaminant, but there still was some therapeutic
23 value. So I think we're saying the same thing. You don't
24 think we are.

25 MR. HONIK: I don't think so. And I think Judge

1 Kugler addressed the argument that a point of adulteration or
2 the recognition of adulteration in 2018 by the FDA is not the
3 seminal point in time that says that's when the drugs could not
4 have been sold.

5 He does not preclude, in fact, he thinks it's facile
6 to not recognize that if the drugs had been sold in that
7 condition, as we now know, from 2012 forward to say that you
8 can't deem it adulterated until the FDA says so. That's not
9 the facts, operative facts of this case.

10 CHIEF JUDGE BUMB: No, I agree. But then that sounds
11 like you're veering -- it sounds like the plaintiff is trying
12 to have it both ways. You're now veering into the but-for
13 territory. Because had the plaintiffs known back then that
14 these were adulterated, they wouldn't have sold it, and they
15 would have gone to another supplier had another supplier
16 existed. The plaintiff can't have it both ways.

17 MR. SLATER: Judge.

18 CHIEF JUDGE BUMB: I must be missing something.

19 MR. SLATER: The issue is if the contamination -- and
20 this has been admitted. I'll start with the ZHP witnesses. I
21 questioned many of them. Every single one of them said if we
22 knew about the contamination and once we knew about it, the
23 pills would never be sold. They've admitted they could never
24 sell the pills with the NDMA and NDEA in it.

25 So when you asked, well, would the plaintiffs, the

1 class members, had bought these pills if they knew about the
2 adulteration, where I had started with is they could not
3 have -- they never would have gotten to the class members.
4 They never would have gotten to the counter. Because if they
5 had disclosed this has NDMA in it, it immediately would not
6 have been able to be marketed.

7 CHIEF JUDGE BUMB: That's right.

8 MR. SLATER: So that's where I was going to say,
9 look, we made the arguments, and Judge Kugler did deny the
10 summary judgment motion --

11 CHIEF JUDGE BUMB: Right.

12 MR. SLATER: -- on the adulteration-ends-the-case
13 issue. But from our perspective, he was being conservative
14 leaving the case for the jury and the fact finder, but we will
15 clearly be making directed verdict motions once the Court has
16 had the benefit of letting the facts be heard on that issue.

17 So that's where I was starting. So I think that's
18 the starting point, but then you get to, okay, if we're not
19 going to get summary judgment on it, on that legal issue, where
20 do we go? And where we go is, I think the question you're
21 asking is a very fair question, do they get to put on proof
22 that there was some value, and that's where Mr. Honik was,
23 which is Judge Kugler did say in a vacuum I'm going to let you
24 try to prove that. There was no ruling that precluded the
25 defense experts from calculating alternative economic damages.

1 CHIEF JUDGE BUMB: Okay. I'll hear from them in a
2 minute.

3 MR. SLATER: They did not do it, as you know, because
4 oftentimes they don't want to create a floor or whatever other
5 reason, maybe they couldn't do it. But they did not do it, and
6 they were not precluded by Judge Kugler from doing it. So
7 without that evidence -- so it's really two levels, not that
8 we're contradicting each other. But I'm saying at the first
9 level, we think, as a matter of law, we should have won but
10 respect the decision. We'll be back again at the end of the
11 evidence with a DV motion.

12 But even before you get there, even though in a
13 vacuum they were given the right in the summary judgment
14 motions, the *Daubert* process for the damages experts had not
15 yet occurred, and that's where we are now. And they do not
16 have any expert who can give the jury a methodology to actually
17 reliably calculate their alternative damage model.

18 CHIEF JUDGE BUMB: So --

19 MR. HONIK: And the language --

20 CHIEF JUDGE BUMB: Hang on one second.

21 So, Mr. Slater, it just seems -- so when you stand up
22 and say that, sure, the defendants can present evidence that
23 the drug had value, but then you also stand up and say, well,
24 we're going to present evidence that these were adulterated
25 let's just say from the beginning and we wouldn't have bought

1 them -- we couldn't have sold -- because they couldn't have
2 been sold, does the plaintiff then just get a free pass?
3 Because the third-party payors would have at some point -- they
4 wouldn't have left their patients, their members, high and dry.

5 So how do you address that issue?

6 MR. SLATER: Because warranty law doesn't say, okay,
7 well, what would you have had to do instead? What would you
8 have bought instead? Warranty law says if you buy something
9 based on a warranty and the warranty was breached, you get your
10 money back.

11 And the warranty law doesn't say, well, what would
12 you have bought otherwise. Otherwise you would never recover
13 in a warranty case where you would have needed to buy a product
14 for that purpose. So that would be -- I don't like to use the
15 word "absurd," but you get what I'm saying. You could never --
16 that's not what the law says. So this but-for world, well,
17 they would have had to buy something anyway, that is not as a
18 matter of law an acceptable legal defense to this.

19 CHIEF JUDGE BUMB: Yeah. And that's if you are
20 pursuing the benefit-of-the-bargain theory, which you are now
21 telling me you are.

22 I mean, the case that I think about is the Volkswagen
23 case. Everybody thought it got 50 miles to the gallon and that
24 it was clean diesel.

25 Well, I'm sure the defendants aren't going to stand

1 up before me and say, well, they would have bought a car anyway
2 or, you know, well, it got 50 miles to the gallon anyway.
3 Because that's to your point, that's why it's a warranty claim.

4 MR. SLATER: Right. We don't think they should be
5 allowed to say that, honestly, to say they would have had to do
6 something else. Because, again, everybody's different. Some
7 people may not have taken pills. Maybe somebody would have
8 taken a different treatment. They would have changed their
9 diet. There's all different treatments.

10 CHIEF JUDGE BUMB: And so that's why I'm pinning you
11 down. It does sound like it's a benefit-of-the-bargain, and
12 that's why the defendant should be permitted to say that the
13 drug had therapeutic value.

14 Yes.

15 MR. HONIK: Your Honor, I just wanted to read the
16 language that I was thinking of that Judge Kugler wrote that I
17 think is very instructive on this point. This is from the
18 Opinion on the decertification, which he denied.

19 "Plaintiffs' theory of damages rests not on a
20 biological basis but on an economics one, that the supply curve
21 of contaminated drugs the FDA never would have allowed for sale
22 is zero, making the drugs unmerchantable," full stop.

23 "Contrary to defendants' characterization,
24 plaintiffs' theory of damages, while not biologically based, is
25 nonetheless based in recognized case law as economic theory."

1 And I think that's instructive because the Court is
2 recognizing that an unmerchantable drug, in this case under the
3 rubric of the FDA regulations which required the drug
4 manufacturers to assure the purity and so forth of the drug so
5 as not to be adulterated, that rendered it unmerchantable. And
6 the fact that it may yet retain some therapeutic or clinical
7 value is of no moment in calculating the damages.

8 CHIEF JUDGE BUMB: Well, it is on your warranty
9 claim.

10 MR. HONIK: I don't -- I don't think that this
11 language --

12 CHIEF JUDGE BUMB: It appears to me -- well, you
13 know, I think the summary judgment came after that.

14 If the plaintiffs' theory is, is that these drugs
15 weren't what they were warranted to be, the defendants should
16 be permitted to introduce evidence that, well, they were. They
17 were therapeutic. They reduce blood pressure.

18 Why should they not be allowed to introduce that
19 evidence?

20 MR. HONIK: I think, Your Honor, they should
21 certainly be permitted to do two things: To demonstrate, if
22 they can, that the drugs were not adulterated. I think the
23 Court has ruled that way. And I think that they should
24 conceptually be permitted to have an expert attempt to present
25 a different economic model that, if it meets the requirements

1 of 702, can get to the jury.

2 We have filed motions to preclude that because try as
3 they have, and I deposed Dr. Stiroh myself, she was incapable
4 of articulating any kind of a formula to embrace economically
5 the idea that there's value associated with a contaminated drug
6 into dollars. And I think it's black letter law that a jury
7 shouldn't be handed a proposition, namely there's some value,
8 and ask them to assign a value that they think is proper.

9 CHIEF JUDGE BUMB: Well, that's a different issue.
10 That's a 702 issue.

11 MR. HONIK: I think that's where we are. I think at
12 the conceptual level, if the Court doesn't, as a matter of law,
13 determine, which we think the Court should, that presenting
14 evidence of, quote, value is speculative, that it falls to the
15 defendants to demonstrate it. We've pointed out very clearly
16 that they have not.

17 And so I think it's a bit circular, but I think it
18 ends up at a point where we get to put in our evidence subject
19 to today's ruling on Dr. Conti, and the defendants, I think,
20 are going to fail to satisfy 702 in order to put some damages
21 in front of the Court that relate to their theory that there's
22 retained value in the drug.

23 MR. SLATER: And I'll just add to that, I think that
24 the thing about this case that makes it from our perspective so
25 straightforward is because of the regulatory overlay.

1 CHIEF JUDGE BUMB: Help me understand that.

2 MR. SLATER: Because the FDA regulations and the
3 actual approval of this drug did not allow the sale of the drug
4 with NDMA or NDEA in it, so therefore there was no legal right
5 to sell it from day one. They did it because nobody knew.

6 We have evidence that we think that -- well, we have
7 evidence that they knew at some point, but the FDA didn't know
8 and the world didn't know. So they were selling this drug.
9 But as the ZHP witnesses all admitted, 30(b)(6) witnesses for
10 the company, if it was known, it could not be sold,
11 unequivocally.

12 CHIEF JUDGE BUMB: If it was known, it could not be
13 sold.

14 MR. SLATER: If it was known that this contamination
15 existed, these pills could not and would not have been sold.
16 No customer would buy it. They never would have sold it. And
17 every witness said and that's why as soon as we found out about
18 this in June 2018, that's why we immediately stopped, went to
19 the FDA, and recalled the drugs because we knew we couldn't
20 sell the drugs once we found out about this.

21 CHIEF JUDGE BUMB: Okay.

22 MR. SLATER: So they've admitted that they couldn't
23 sell the pills; that there is no legal market. It's not just a
24 warranty issue with a consumer product, but this is a
25 regulatory overlay. And all of the guidances and all of the

1 regulatory rules, I'll call them, ICH and all the others,
2 unequivocally said that the NDMA and NDEA could not be in these
3 drugs. The tolerance level was zero. After this came out, the
4 FDA said, all right, we're going to allow these tiny amounts
5 moving forward. But for this trial it's not a problem because
6 everything exceeded those levels, so we don't have to worry
7 about that.

8 CHIEF JUDGE BUMB: But I think that it matters
9 whether or not there was fraud involved. It just seems to me
10 that if the defendants did not know that these were
11 contaminated at the time, for the plaintiffs to be able to
12 prevail on, well, we should be able to go all the way back and
13 say they were worthless when no one knew they were worthless.

14 Now, if there was fraud involved, then you're into a
15 different -- you're into fraud territory. But I'm having a
16 hard time understanding why it is that the plaintiffs should be
17 able to say, well, these drugs should never have been sold
18 because the FDA -- because they were contaminated for years,
19 and therefore we get the entire -- we get the entire refund,
20 when clearly the members would have -- the plaintiff would have
21 had to pay for an alternative drug. And that's where perhaps
22 your theory is different with respect to merchantability as it
23 is with respect to benefit-of-the-bargain/warranty, and maybe
24 that's how I can reconcile these two different positions that
25 the plaintiff seems to be arguing.

1 MR. SLATER: Well, there's two things at work there.
2 One is the idea that the plaintiff would have had to get
3 something else really is from our perspective, I think, legally
4 irrelevant, because the issue is the defendants sold their drug
5 and they're responsible for the damages they caused, number
6 one.

7 Number two, warranty and consumer protection, which
8 are two of the three claims at issue, do not have intent as an
9 element. So we don't have to prove intent, and that's why
10 warranty law is as it is. Because if you had to prove intent,
11 there would be so many warranty cases where they would say,
12 well, we just didn't know.

13 CHIEF JUDGE BUMB: So then we just get back to
14 they're entitled to prove that they had value. Right.

15 MR. SLATER: I think that where we end up practically
16 because of the rulings that have taken us to here is that the
17 lay of the land is that Judge Kugler's rulings allow them to
18 say there was therapeutic value.

19 CHIEF JUDGE BUMB: Yeah.

20 MR. SLATER: And, however, that is subject to what
21 you're about to look at in these *Daubert* hearings with the
22 economic damages experts where they literally don't have an
23 expert who actually does establish a reliable methodology and
24 calculation to do that.

25 So Judge Kugler left the door open for the trial.

1 Again, we feel very confident that we're going to have very
2 strong motions at the end of the evidence when the standard is
3 different when now the facts have been heard and the Court has
4 heard the facts, and they've had every chance to try to
5 establish the things they've said we might be able to
6 establish, but...

7 CHIEF JUDGE BUMB: Well, it sounds like in the
8 conversation that we're having, and I'm going to ask the
9 defendants to speak, the argument that had the FDA known back
10 then what it then knew, it may not even be relevant. It may
11 not be an argument the jury should hear.

12 MR. SLATER: Well, however it's raised, the
13 regulations, the regulatory framework that governed these drugs
14 would not allow them to be sold because it was not legal to
15 sell them.

16 CHIEF JUDGE BUMB: Right. I agree with that. But it
17 may not be relevant because those weren't the facts. It comes
18 down to: Were they therapeutic or not? Was there a
19 misrepresentation?

20 MR. SLATER: Well, when you say it wasn't the facts,
21 the facts were that the regulation did not permit the sale of
22 these drugs. They never were permitted because they had NDMA
23 and NDEA in it.

24 CHIEF JUDGE BUMB: Correct.

25 MR. SLATER: The fact that the company sold them,

1 whether they knew it or not, doesn't make it right and doesn't
2 entitle them to not have to pay damages to people that bought
3 these drugs that should not have been sold.

4 And there's no world in which anybody's going to
5 stand up -- you're not going to hear one defense witness stand
6 up and say it was okay. The FDA regulations, which would
7 govern these drugs, so that has to be part of the case, you
8 can't jettison it out because that's what regulated the sales
9 of these drugs. There's no witness who's going to say, well,
10 you know, under those regulations, we could have sold these
11 drugs and let me tell you how.

12 CHIEF JUDGE BUMB: They're not going to say that, but
13 they're going to say, I presume, because the briefing seems to
14 be all over the place, I'll just say, it seems to me they're
15 going to get up and say we agree that had we known, we couldn't
16 have sold them. We didn't know and the FDA didn't know. And
17 so to stand before the jury and say our damages should be zero
18 from the get-go because they should never have been sold in the
19 first place presumes several things; that everybody knew that
20 there was this contaminant, that -- and then --

21 MR. SLATER: But those just aren't elements of the
22 claim. Intent or knowledge is not an element of either the
23 consumer protection or warranty claims.

24 CHIEF JUDGE BUMB: I'm having a hard time.

25 MR. SLATER: They're very simple claims. You said it

1 was this. It wasn't. You recover.

2 CHIEF JUDGE BUMB: I'm having a -- here's what -- I'm
3 going to leave it at this.

4 MR. SLATER: The fraud claim you're right on. I
5 agree on the fraud claim we have to prove that they had
6 knowledge, and we're ready to go on that.

7 CHIEF JUDGE BUMB: I'm having a hard time
8 understanding how it is that the plaintiff can stand before the
9 jury and say they should never have been sold in the first
10 place; therefore, we get everything. That's -- that's the
11 problem I'm having.

12 Okay. Let me hear from the defendants.

13 MS. ALLON: Thank you, Your Honor.

14 So there are two damages arguments, primary damages
15 arguments, which are distinct, and I think it's important to
16 treat them separately. The first argument is that the pills
17 were not worthless because they had some therapeutic value,
18 right.

19 CHIEF JUDGE BUMB: Okay. What's that damage claim,
20 benefit of bargain?

21 MS. ALLON: Yeah. Yeah. Absolutely.

22 CHIEF JUDGE BUMB: Okay.

23 MS. ALLON: Judge Kugler, crystal clear on this
24 topic, right. It's page 58 of the summary judgment decision.
25 He says there's a genuine dispute of material fact as to the

1 amount of TPP damage, which centers on whether the damages are
2 nothing because they gave the TPPs what they paid for, lowered
3 blood pressure, right, that's therapeutic value, or are they
4 worthless. That's this debate, right? Judge Kugler said it
5 comes in.

6 I'm a little bit surprised that the plaintiffs are
7 now saying they have a *Daubert* argument because they're not
8 moving to exclude that opinion by Dr. Stiroh. In their -- in
9 the *Daubert* briefing, this is ECF-2673, that's at their reply
10 brief, they said: Dr. Stiroh's other primary opinion is not
11 the subject of this *Daubert* motion; that the VCDs had some
12 non-zero economic value because they purportedly delivered some
13 therapeutic benefit. That opinion is not subject to a *Daubert*.

14 CHIEF JUDGE BUMB: It hasn't been challenged?

15 MS. ALLON: It hasn't been challenged. It's not
16 subject to a motion in limine. So Judge Kugler said there's a
17 disputed issue of fact. The plaintiffs haven't challenged it
18 under 702. So as far as I can tell, it's coming in. That's
19 opinion number one.

20 CHIEF JUDGE BUMB: Where is that admission?

21 MS. ALLON: It's ECF-2673 at page 4. That's their
22 plaintiffs' damages *Daubert* reply brief.

23 CHIEF JUDGE BUMB: Okay.

24 MS. ALLON: Okay. So that's that opinion.

25 There's another argument. The other argument is that

1 Dr. Conti should have considered the cost of alternatives,
2 right? If TPPs hadn't reimbursed for these products, they
3 would have had to reimburse for other products, and she didn't
4 take that into account.

5 CHIEF JUDGE BUMB: Okay. I don't agree with --
6 that's your argument.

7 MS. ALLON: Yeah, that's the second defense damages
8 argument.

9 CHIEF JUDGE BUMB: Well, I'm just going to -- maybe
10 I'll shortcut this a little bit or maybe I'll extend it. I
11 don't know. Sometimes when I say things it tends to extend
12 things. But I don't agree with that on the warranty, and the
13 reason I don't agree with it on the warranty claim on the
14 benefit-of-the-bargain, because then that just gives -- if a
15 defendant represents a product to be so and it's not so, and
16 then the argument is, well, you would have had to buy it
17 anyway, you would have had to buy a car anyway, then that just
18 gives the defendants a free pass.

19 MS. ALLON: So I hear you, Your Honor. I think the
20 situation is a little bit different. I agree that the
21 plaintiffs are pursuing a benefit-of-the bargain theory. I
22 agree.

23 CHIEF JUDGE BUMB: Okay.

24 MS. ALLON: There is a dispute over what the bargain
25 is. And that dispute, what is the bargain that was struck, is

1 a fact question for the jury. That is clear.

2 CHIEF JUDGE BUMB: What's the fact question?

3 MS. ALLON: The question is, given that the
4 plaintiffs are not people ingesting this product, they are
5 companies that are reimbursing for this product, right?
6 Dr. Stiroh's opinion is that so long as they were able to
7 satisfy their coverage obligations, the bargain was that they
8 would be able to satisfy their coverage obligations, and if
9 they were able to satisfy their coverage obligations with a
10 less expensive alternative, then they have received the benefit
11 of their bargain.

12 The plaintiffs and the defendant are allowed to
13 disagree over what the bargain is. The plaintiffs can present
14 their theory, and the defendants should be entitled to present
15 their theory.

16 CHIEF JUDGE BUMB: So the defendants are going to
17 stand up before the jury and say: Well, we don't really care
18 what the drugs did. As long as we provided them a low-base
19 drug, we're okay?

20 MS. ALLON: What Dr. Stiroh is going to say is that
21 because the plaintiffs received alternative products likely at
22 a lower cost --

23 CHIEF JUDGE BUMB: Yeah.

24 MS. ALLON: -- they were not deprived of the benefit
25 of their bargain.

1 CHIEF JUDGE BUMB: Well, that's just a circular way
2 of saying that they provided a value, and so we're kind of back
3 to where we were.

4 You can't just stand up -- the defendants just can't
5 stand up and say, oh, well, we just gave them, you know, we
6 just gave them a low-base product, and so no case, no
7 controversy, sit down. I mean, what is that low-base product
8 you provided, something that was adulterated or not?

9 MS. ALLON: No, no. We all agree the alternative --
10 we all agree that the alternative is unadulterated, right? The
11 alternative product is unadulterated blood pressure medication.
12 We all agree with that.

13 CHIEF JUDGE BUMB: Okay.

14 MS. ALLON: And what Dr. Stiroh is going to say is
15 that Dr. Conti should have considered that, and she didn't.
16 It's a criticism of the plaintiffs' model.

17 And I think actually there's only one decision that
18 is on point on this topic, because many of the decisions really
19 are not on point. They're talking about other issues.

20 The one decision that is on point is the *Blue Cross*
21 *Blue Shield* decision from the Eastern District of Pennsylvania,
22 and in that case the Court ruled that to the extent GSK, who
23 was the defendant in that case, wants to argue that the
24 plaintiffs' damages calculation has to deduct for the cost of
25 therapeutic alternatives, that this is a decision for the jury

1 to decide at trial based on evaluation of the parties'
2 conflicting expert testimony. That's at 559. That's the only
3 decision we have that's on point. Because, again --

4 CHIEF JUDGE BUMB: I know. But you're trying to
5 frame the representation too narrowly. It seems to me you're
6 trying to frame the representation that was made by the
7 defendants to the plaintiffs is that we will provide you a
8 lower-cost drug, period. No. We will provide you a lower-cost
9 drug that is unadulterated.

10 MS. ALLON: Well, but, Your Honor, there can be a
11 breach of warranty without corresponding damages. The damages
12 question is not the same thing as the liability question.

13 CHIEF JUDGE BUMB: You really aren't -- you're really
14 not standing before me and telling me that the plaintiffs'
15 claim is that -- that the plaintiffs' breach of warranty claim
16 is that you were supposed to provide us with the lower-based
17 drugs and you didn't, period.

18 Is that what you're saying?

19 MS. ALLON: The plaintiffs' claims is --

20 CHIEF JUDGE BUMB: Because we may have to just start
21 over from scratch.

22 MS. ALLON: The plaintiffs' warranty claim is you
23 were supposed to provide us with drugs that didn't have NDMA
24 and you didn't, and therefore we're entitled to the full cost
25 of those drugs.

1 CHIEF JUDGE BUMB: Oh.

2 MS. ALLON: That's their claim.

3 CHIEF JUDGE BUMB: Okay.

4 MS. ALLON: But we're entitled --

5 CHIEF JUDGE BUMB: That's something different from
6 what you just said.

7 MS. ALLON: Well, but the defendants are entitled to
8 respond to that and say, no, what the actual bargain was, was
9 that you would be able to reimburse your members' drug
10 prescription costs and you were at a lower cost. And therefore
11 there's no economic injury. That's a -- that's a rebuttal to
12 their damages argument. I don't see why the defense isn't
13 permitted to challenge the claim of economic injury.

14 Because, by the way, if the plaintiffs are entitled
15 to do what they want to do so they can get a windfall, right?
16 They can recover the full cost while they also spent less money
17 on alternatives. We know that's not true. We know that
18 violates basic damages principles.

19 CHIEF JUDGE BUMB: Let me just read what you just
20 said.

21 Okay. I guess you could make that argument.

22 MS. ALLON: And --

23 CHIEF JUDGE BUMB: But that just -- okay.

24 MS. ALLON: And then the last point that I'll make
25 is, when we're talking about this opinion, the plaintiffs do

1 have a challenge, which is essentially there's no methodology,
2 right? We don't offer -- I think I heard somebody say we don't
3 have an alternative number, right? And I would say that's not
4 our burden, right? We're entitled to poke holes in their
5 damages case. We don't have to offer our own damages model.
6 We're entitled -- Dr. Stiroh, as a rebuttal expert, is entitled
7 to say, look, I think Dr. Conti should have considered it.

8 By the way, the plaintiffs could have provided a more
9 nuanced model. They just chose all or nothing.

10 CHIEF JUDGE BUMB: Well, I think we're -- we'll get
11 to Conti, but I think the fight about Conti is much to-do about
12 nothing, to be perfectly candid. I think that she can assume
13 that they were worthless. Because the jury is going to decide
14 whether they were or not. She can decide whether they were
15 worthless, and then she can do her analysis based upon that
16 they had no value.

17 I think there's issues with the unjust enrichment
18 claim. But when we get to her, I'm just going to skip through
19 this all "assuming they were worthless." She can assume they
20 were worthless.

21 MS. ALLON: So I agree, Your Honor. I think the real
22 fight is about Dr. Stiroh, frankly, not Dr. Conti.

23 CHIEF JUDGE BUMB: Okay.

24 MS. ALLON: The real fight is, well, what can
25 Dr. Stiroh say in response? Once Dr. Conti is permitted to say

1 that, what can our expert say in rebuttal?

2 CHIEF JUDGE BUMB: Okay.

3 MS. ALLON: And that's the point I'm trying to make;
4 that we should have the right to rebut their damages model by
5 saying there's something they should have considered that they
6 didn't.

7 CHIEF JUDGE BUMB: I think we're agreeing on
8 everything. It just doesn't seem like we are.

9 MR. HONIK: Your Honor, I think counsel misspoke at
10 the beginning.

11 CHIEF JUDGE BUMB: Yeah.

12 MR. HONIK: And I commend to Your Honor ECF-2694.
13 That was a summary or is a summary judgment ruling that Judge
14 Kugler made --

15 CHIEF JUDGE BUMB: Yeah.

16 MR. HONIK: -- that a warranty exists in this case
17 that runs to the TPPs. So there's no question about that.

18 CHIEF JUDGE BUMB: No, I don't think she's disputing
19 that. She's disputing what that warranty itself was.

20 They are -- they, the defendants -- and I don't know
21 why. I'd have to, I guess, go back and look at the complaint,
22 but they are framing the warranty as you, defendants, agree to
23 provide us low-cost drugs. We've provided them, so what's the
24 issue?

25 Plaintiffs are saying, no, the warranty was you

1 agreed to provide us low-cost base drugs that did not have NDMA
2 in them.

3 MR. HONIK: We're actually saying that and more.
4 We're saying the FDA doesn't permit their warranty proposition.
5 The FDA literally does not allow a low cost drug that is
6 adulterated.

7 And what Dr. Conti will testify about --

8 CHIEF JUDGE BUMB: Yeah, I think that they will have
9 a very hard time persuading a jury of that.

10 MR. HONIK: So now we're full circle, and we are in
11 agreement that we're talking about benefit-of-the-bargain.

12 CHIEF JUDGE BUMB: Yeah.

13 MR. HONIK: Here's the essential point, Your Honor,
14 respectfully. The measure for benefit-of-the-bargain damages
15 is objective. There is no scienter whatever. The question is
16 simply what was the value given versus what should have been
17 received.

18 CHIEF JUDGE BUMB: I think we are all saying the same
19 thing.

20 MR. HONIK: And the economist in this case is saying,
21 because the FDA precludes, and all the defendant pharmacy
22 retailers, everyone agrees, frankly, that you're not permitted
23 to put adulterated drugs in the stream of commerce, that the
24 value from an economic standpoint is zero. And so the delta
25 between that value objectively determined and the price are the

1 damages.

2 CHIEF JUDGE BUMB: And I don't agree with that
3 because now I think you get into the but-for.

4 I think there comes a point in time where, if the
5 drug had been recalled, it wouldn't have been put into the
6 stream of commerce. And, therefore, there is -- there is a
7 different analysis.

8 I think, unless you folks persuade me differently, I
9 think there is -- you can't pretend as if these drugs should
10 never have been sold in the first place. I think on the breach
11 of warranty, you get into the value issue, whether or not these
12 drugs had any value. But to stand before the jury and say we
13 get it all because they never should have sold them in the
14 first place, a jury should be able to say, well, did they know
15 they should never have been sold in the first place and when
16 did they know, and that becomes your measure of damages,
17 because otherwise you're back into breach of warranty land.
18 That's -- that's just how I see it.

19 Because I don't -- you'll have to persuade me
20 differently, but for the plaintiffs to stand before and say,
21 well, they should get a full refund because these shouldn't
22 have been sold in the first place, unless there is a breach of
23 warranty and unless there is scienter, it seems to me the
24 plaintiffs get an unnecessary windfall.

25 MR. SLATER: Your Honor, let me, because I know

1 you're focused on when did they know and should that matter.
2 That's the cGMP piece of this case. They don't get a pass for
3 being ignorant of what they were selling, that it had poison in
4 it. They, under cGMPs, one of the violations that the FDA
5 found and made the finding that they violated cGMPs and as a
6 result the drugs were adulterated, one of the primary
7 violations the FDA found was the failure by ZHP to perform an
8 adequate risk assessment as required by cGMP.

9 So there's no -- first of all, there's no scienter
10 requirement in the cause of action. And under the regulatory
11 law, as the FDA found it, and I don't think you're going to
12 have a witness who's going to argue this for the defense, that
13 the lack of a risk assessment would be immaterial. That is
14 what stands between -- or basically is the answer to what your
15 question, which is --

16 CHIEF JUDGE BUMB: What is the claim? What is the
17 claim?

18 MR. SLATER: For why it's adulterated?

19 CHIEF JUDGE BUMB: Other than the breach of warranty,
20 other than the warranty claims. What's the claim?

21 MR. SLATER: There's three claims in this case: The
22 breach of express warranty.

23 CHIEF JUDGE BUMB: Yeah.

24 MR. SLATER: The consumer protection.

25 CHIEF JUDGE BUMB: Yeah.

1 MR. SLATER: And the fraud.

2 CHIEF JUDGE BUMB: Okay.

3 MR. SLATER: And the FDA found you, ZHP, the warning
4 letter actually goes through it and says: You say you didn't
5 know and nobody could have known because it wasn't something
6 understood. And the FDA said we disagree, because you are
7 responsible for the quality of your drugs and you're
8 responsible to do a risk assessment and to know what's in your
9 drugs.

10 And the person that I deposed, Eric Gu, who runs the
11 part of ZHP that actually developed this process, that's the
12 main process at issue, admitted that if they had found that
13 there was NDMA being produced during this process, they would
14 have had to stop the process, and they would have had to scrap
15 the project and go back and reformulate the manufacturing
16 process they were creating because they could not have sold
17 this with NDMA in it.

18 So this is not us saying that they couldn't do it and
19 defense is going to say, well, it was okay that we sold it.
20 They're not saying that. Their own witnesses are saying that
21 they needed to know. And their own witnesses are saying that
22 they had to do an adequate risk assessment.

23 They try to argue about why they didn't learn these
24 things, but scienter or knowledge is not an element. It's not
25 an element of the claim, and it's not an element under the

1 regulatory construct that governed their development and sale
2 of the drugs with the manufacturing process that they
3 developed.

4 They have to develop that process the right way with
5 a proper risk assessment, and in this case the lack of risk
6 assessment was they didn't evaluate the chemical reactions,
7 which they should have done and the FDA said they should have
8 done, because they, as they've admitted, their 30(b)(6)
9 witnesses, they were responsible for the quality of their drugs
10 and could not have sold it as soon as that would have been
11 shown. And the risk assessment, if done right, would have
12 shown it.

13 CHIEF JUDGE BUMB: What claim does that go to?

14 MR. SLATER: It goes to -- well, it definitely -- it
15 goes to probably -- it certainly goes to the warranty claim.

16 CHIEF JUDGE BUMB: Okay.

17 MR. SLATER: Look, we don't even think you need to go
18 that far, but --

19 CHIEF JUDGE BUMB: But you have to tie what you're
20 presenting to the jury to the claim.

21 MR. SLATER: Right.

22 CHIEF JUDGE BUMB: The breach of warranty, I don't
23 think there's a -- I think we've all agreed now, the breach of
24 warranty is that the plaintiffs are permitted to say they have
25 absolutely no value, and the defendants are permitted to say

1 they had a value.

2 What are the other two claims? Because it does
3 become relevant, I think, for the causes of action as to when
4 the defendants knew or whether there was fraud.

5 MR. SLATER: Or should have known.

6 CHIEF JUDGE BUMB: Otherwise it becomes a strict
7 liability.

8 MR. SLATER: Or should have known based on a proper
9 risk assessment.

10 CHIEF JUDGE BUMB: Okay. Fine.

11 MR. SLATER: And that's the rub that I think is
12 maybe --

13 CHIEF JUDGE BUMB: Okay. Fine. But a jury has got
14 to make that determination in terms of calculating damages.

15 MR. SLATER: Well, look, because there's been a lot
16 that's happened, we don't think, as a matter of law, that we
17 should even have to prove cGMP violations because we know we
18 have an FDA ruling of adulteration and we know that every pill
19 was adulterated. You can't say the pills were not adulterated
20 before the FDA said they were adulterated because they had NDMA
21 in it from day one. But we were told by the Court, I'm not
22 going to grant you a ruling that cGMP is not a part of this
23 case. So it's in the case as of now.

24 CHIEF JUDGE BUMB: It is in the case, but it also
25 doesn't mean that just by showing that they violated the

1 cGMPs --

2 MR. SLATER: Well, the violation is a reason for
3 adulteration. That's what the FDA found.

4 CHIEF JUDGE BUMB: I know. But you're somehow
5 turning your cause of action into a strict liability. That's
6 the issue that I'm trying to --

7 MR. SLATER: Well --

8 CHIEF JUDGE BUMB: It seems to me that it becomes
9 relevant to the jury's determination of damages as to -- the
10 breach of warranty I think we're clear on. The other two
11 violations, I'm going to have to get briefing on this, because
12 I think it sounds more like strict liability to me, and that
13 does not seem to comport with what I understand the case law to
14 be.

15 MR. SLATER: Well, a warranty claim really is
16 basically a strict liability claim. You sold something, you
17 said it was this --

18 CHIEF JUDGE BUMB: True.

19 MR. SLATER: -- and it wasn't. So it really is, it
20 really is, and I think that the state of mind --

21 CHIEF JUDGE BUMB: Well, when I say --

22 MR. SLATER: -- element that Your Honor is
23 questioning, that is supplied, because we don't think it should
24 be a part of the case but is in the case right now. That is
25 addressed by the cGMP piece of it and by their internal

1 documents showing what they knew and when they knew it and
2 everything else. But you're concerned about when did they know
3 it and that being the case.

4 CHIEF JUDGE BUMB: I know, but what I'm saying is I
5 don't think that any party has helped me in tying these
6 disputes to the causes of action and the elements. Breach of
7 warranty, it's pretty well understood what breach of warranty
8 is. I represent this, and the representation is false. Okay.
9 You folks will argue about whether or not the drug was
10 therapeutic or no or not.

11 The other two causes of action, what are they? What
12 are the elements? And what does the defendant have to prove?

13 MR. SLATER: The consumer protection is very similar.

14 CHIEF JUDGE BUMB: Yeah. That has a fraud element in
15 it.

16 MR. SLATER: Well, we're not trying a consumer -- a
17 scienter we knew it's fraudulent consumer protection.

18 CHIEF JUDGE BUMB: Okay.

19 MR. SLATER: It's very similar to the warranty claim
20 in terms of what they said. And they did affirmatively
21 represent, by the way, this is USP quality valsartan, which
22 Judge Kugler's already ruled in the warranty claim that is a
23 warranty as a matter of law that they gave.

24 CHIEF JUDGE BUMB: Okay.

25 MR. SLATER: It's the statement they made here, that

1 was an affirmative misrepresentation.

2 There's no element of knowledge that they -- when you
3 make an affirmative misrepresentation like that for consumer
4 protection purposes, the act of making that representation, we
5 don't have to prove they knew it was false. We just have to
6 prove they made a false statement and induced people to buy
7 based on that statement.

8 The fraud claim we are going to show.

9 CHIEF JUDGE BUMB: What's the other cause of action
10 in this?

11 MR. SLATER: Fraud, common law fraud.

12 CHIEF JUDGE BUMB: Other than breach of warranty,
13 what's the other cause of action?

14 MR. SLATER: Consumer protection.

15 CHIEF JUDGE BUMB: Okay.

16 MR. SLATER: And then the last cause of action is
17 common law fraud.

18 CHIEF JUDGE BUMB: Okay. So that's why I'm saying
19 all of these, the last two have a scienter element to them.

20 MR. HONIK: And Mr. Davis can address the elements.

21 MR. SLATER: One second.

22 CHIEF JUDGE BUMB: And to stand up and say, well, no,
23 we got to rely on the regs, you can't sell them, period, end of
24 story, I think does not address the elements of the causes of
25 action.

1 MR. SLATER: I'm not saying that for the common law
2 fraud claim.

3 CHIEF JUDGE BUMB: Okay. What are you saying it for?

4 MR. SLATER: I would say it for the warranty claim,
5 scienter is not a factor.

6 CHIEF JUDGE BUMB: Agreed.

7 MR. SLATER: State of mind is not a factor.

8 CHIEF JUDGE BUMB: Agreed.

9 MR. SLATER: For the common law fraud claim, there's
10 an argument that can be made that maybe you don't have to go
11 all the way to that, if you just don't want to know it's there,
12 maybe it's fraud, but we're going to prove anyway they had
13 knowledge.

14 CHIEF JUDGE BUMB: Okay.

15 MR. SLATER: We have documents that show knowledge.

16 CHIEF JUDGE BUMB: Okay. So I think you've -- I
17 think you've assuaged my concerns.

18 MR. SLATER: Okay.

19 CHIEF JUDGE BUMB: Which is the plaintiff cannot get
20 up and say in a vacuum that its case is met by relying on the
21 FDA regs that these are adulterated, they shouldn't have been
22 sold, period. You got to do more than that with respect to
23 these causes of action.

24 MR. SLATER: Definitely for the fraud claim, the
25 common law fraud claim we do. I don't think we need to do more

1 for the warranty claim for the reasons we've explained.
2 Mr. Davis, to the extent you have questions about the consumer
3 protection claim, he can answer those questions because he's
4 more familiar with all the standards and he can explain it and
5 he's briefed a lot of that. But I think it falls very similar
6 to the warranty claim. It basically ends up in the same place,
7 but if you want more information, Mr. Davis can provide that,
8 Your Honor.

9 MR. DAVIS: We're not arguing that we don't have to
10 prove all of the other elements of liability. This is strictly
11 as to the damages element. And for breach of warranty, for
12 fraud, for the common law fraud -- or the consumer protection
13 claims, that standard is benefit-of-the-bargain. The
14 defendants themselves have agreed to that. And so it's going
15 to be the same objective inquiry of looking at the value of
16 these drugs as represented versus the objective value they had
17 when sold at the point of sale, which is what the damages
18 analysis is.

19 And you'll hear from Dr. Conti. She's going to get
20 up there and say that this isn't some counter-factual, but-for
21 world we're modeling. She's looking at the objective value
22 that these drugs had when sold, because they were sold. They
23 were sold. And that's what gives rise to the causes of actions
24 here.

25 And so, you know, Congress, as a matter of

1 congressional policy, has set a value of zero to these drugs by
2 deeming the adulterated drugs illegal to sell. That's just an
3 economic basis for saying that they had zero value at the point
4 of sale from an objective economic standpoint.

5 CHIEF JUDGE BUMB: Well, do you agree, though, that
6 that should not preclude the defendants from saying that, yes,
7 we could not have sold them, we didn't know we couldn't have
8 sold them, we didn't know that they were adulterated, but in
9 any event, for the past umpteen years, they had a value? They
10 should be permitted to say that; you agree with that?

11 MR. DAVIS: Your Honor, I think it's important to go
12 back to an expert that the defendants tendered at class
13 certification. Her name was Punam Keller. She's a marketing
14 professor out of Dartmouth. She put forward a report saying
15 that if, you know, in some hypothetical world, you could do a
16 consumer study and the consumers might ascribe some economic
17 value to these drugs. But she didn't do that study. I think
18 we all know whether --

19 CHIEF JUDGE BUMB: Yeah. And that's another -- I
20 mean, that's an issue. I mean, I think that -- well, okay.

21 MR. DAVIS: And so Judge Kugler struck -- correctly
22 struck her opinion as a lot of "I think so" and speculation
23 about value, but she didn't have an actual methodology or any
24 results to actually come up with a number to ascribe some
25 economic value.

1 And I'll say my own reason for thinking why the
2 defendants didn't do that is because a properly designed study
3 would have said look at the value of what you got, adulterated
4 valsartan, versus what their comparative would have been, which
5 is non-adulterated valsartan. Of course, every consumer would
6 have wanted to pick the version that didn't have the carcinogen
7 in it that does the exact same thing.

8 So the defendants have been on notice for several
9 years now that they need to put forward an expert that actually
10 can take all these points that they're trying to make and tie
11 them to objective economic value, and that's not what's been
12 done here.

13 CHIEF JUDGE BUMB: Thank you.

14 MR. DAVIS: One more point, Your Honor.

15 Ms. Allon, I think you'll stand up again after I say
16 this, she brought up the BCBS case. And the whole theory of
17 alternative drugs is a different -- this is different from
18 value, because value, in some conceptual sense, like Mr. Honik
19 said, is something that can be imported into the
20 benefit-of-the-bargain damages analysis. Replacement drugs
21 cannot because -- and the defendants have cited RICO cases.
22 They've cited antitrust cases where the case -- the whole
23 theory of the case was modeling a market impact. That's not
24 what this case is about. This case is about valuing these
25 drugs actually as they were sold.

1 And so what Judge Sanchez did in BCBS is he rejected
2 GSK's argument that Dr. Conti should have accounted for
3 alternative drug prices. He said she doesn't have to do that.
4 He did say that GSK could present their own theory, but that
5 wasn't something that was actually before him. That was dicta.
6 The plaintiffs in that case did not have a Motion in Limine 16
7 like we have here, and there was no summary judgment that was
8 filed by plaintiffs. They didn't move for a motion in limine
9 at all on that.

10 And so I think if you take the crystallization of
11 what that ruling is, is that he was nonplussed with the
12 argument. He said Dr. Conti does not need to account for this
13 in this warranty case. It does not need to -- the defendants,
14 sure, they can argue it, but there was nothing before him to
15 actually preclude them from arguing it.

16 Judge Kugler explicitly adopted Judge Sanchez's
17 ruling, even quoted from it and said he disagreed with the
18 defendants' position. And, therefore, it's already been ruled
19 on that Dr. Conti and plaintiffs in this case don't have to
20 account for alternative drugs, and the reason for that is that
21 this isn't -- we're not modeling a but-for world here.

22 CHIEF JUDGE BUMB: Okay. Thank you, Mr. Davis.

23 Well, yes.

24 MS. ALLON: I don't have to respond, if you...

25 CHIEF JUDGE BUMB: Well, I'm just going to give you

1 the benefit of my thinking, and then I want to get to the
2 witness, because I want -- I just -- we have to move on. And,
3 you know, it's -- I don't know how I -- I don't know how I fix
4 this disconnect at this late stage of the game.

5 But it just seems to me, to the extent that the
6 plaintiffs want to get before the jury and say that these drugs
7 have no value, that they should never have been sold, period,
8 because the FDA says the regulations are that you don't sell
9 adulterated drugs, which no one disputes, it just seems to me
10 that absent evidence of knowledge or scienter on the part of
11 the defendants that they knew they were adulterated and still
12 sold them, the defendants should be permitted to argue that
13 these drugs had therapeutic value. I don't think that they
14 should be prevented from arguing that.

15 And I don't think the fact that -- that's the case.
16 And I don't think the fact that the -- I don't accept the
17 argument that, well, the plaintiffs, you know, get zero because
18 they would have had to buy alternative drugs. I don't find
19 that persuasive. I think that just -- you know, then why do we
20 have causes of action? I find that that just totally does
21 violence to the causes of action of warranty.

22 MS. ALLON: So, Your Honor, with all due respect, I
23 appreciate that you don't find it persuasive. A jury may not
24 find it persuasive. But that doesn't mean it's not an issue
25 for the jury, right?

1 The defendants are allowed to submit to the jury that
2 the bargain is different than what the plaintiffs are arguing.
3 That's what the restatement of torts means when it says the
4 nature of the bargain is an issue for the fact finder.

5 CHIEF JUDGE BUMB: Oh, that is.

6 MS. ALLON: Okay. And so --

7 CHIEF JUDGE BUMB: And it may very well be that
8 there's going to be a roadmap for the jury. What do you find
9 the representation to be? If you find it this, then...

10 Okay. Fair enough.

11 MS. ALLON: Okay. So --

12 CHIEF JUDGE BUMB: I mean, but I don't -- I'm not
13 going to let you present that argument to the jury, because
14 what I'm hearing you say is, well, no, what they're suing us on
15 is that we said that we -- that the defendants would sell us
16 low-cost drugs, period. And you're going to get up before the
17 jury, and the whole trial is going to be about are these
18 low-cost drugs or are these Cadillac drugs. Because I'm going
19 to resolve that issue before we even go to a jury because I
20 don't -- that's never how I've understood this case in terms of
21 their warranty claim. So that's --

22 MS. ALLON: That's -- that's fine, Your Honor. But
23 Dr. Stiroh has an opinion -- it's paragraph 32 of her report --
24 which is about the nature of the bargain. And she -- that's a
25 response to the plaintiffs. And so they say the bargain was

1 one thing, we say the bargain was another, and the jury will
2 assess the credibility.

3 And by the way, I --

4 CHIEF JUDGE BUMB: I know. You really want to get up
5 before the jury and say that the -- that the only thing that we
6 have promised them was that we were going to sell them low-cost
7 drugs, and it didn't matter if they had cancer-causing agents
8 in them.

9 MS. ALLON: What I want to tell them --

10 CHIEF JUDGE BUMB: Is that what you're going to
11 argue?

12 MS. ALLON: What I want to tell them is, and what
13 Dr. Stiroh is going to testify about tomorrow, is that the
14 plaintiffs are TPPs. They are not, as we all acknowledge,
15 ingesting medication. What they are doing is providing a
16 benefit to their members. And so what matters to them is can
17 they provide that coverage benefit to their members at the same
18 or lower cost, right?

19 And so, therefore, the question we have to ask
20 ourselves is, did the defendants' conduct deprive them of the
21 benefit of that bargain?

22 CHIEF JUDGE BUMB: I'm just going to say this: I
23 think that argument is a little specious. Because unless
24 you've got evidence that the TPPs could care less what they
25 buy --

1 MS. ALLON: We do. We do, Your Honor.

2 CHIEF JUDGE BUMB: They don't care what they buy?

3 MS. ALLON: We have evidence from TPP testimony.

4 This is part of Dr. Stiroh's methodology. Do I think it
5 matters to a TPP whether they prescribed valsartan or some
6 other ARB? No, I don't think it does. What I think matters to
7 the TPP is what is the cost. And so --

8 CHIEF JUDGE BUMB: Solely. Solely. They don't care
9 if the cost -- if the cost is \$2 versus \$10, they don't care if
10 it's adulterated or not?

11 MS. ALLON: No, but if the question is what is their
12 injury, if their alternative was providing a higher-cost
13 medication, then they haven't been injured. That goes to the
14 question of is there economic injury.

15 CHIEF JUDGE BUMB: You're losing me on that one.
16 That's just not an argument I don't think I'm going to allow to
17 be made.

18 MS. ALLON: Okay. Well, obviously, we have the
19 experts here, right.

20 CHIEF JUDGE BUMB: We'll flesh it out more with your
21 experts, because I'm going to be a little shocked that your
22 expert kind of goes like this and just doesn't, you know, the
23 TPPs really don't care what kind of a drug it is, as long as
24 it's \$2. That is a big wow.

25 MR. SLATER: No. I can tell you, Judge --

1 CHIEF JUDGE BUMB: That's a big wow.

2 MR. SLATER: There's no surprise. There's a
3 formulary for every insurance company, and the formulary is the
4 list of the approved drugs. Every one of them is approved USP
5 Orange Book --

6 CHIEF JUDGE BUMB: Yeah.

7 MR. SLATER: -- rated drugs. And that's --

8 CHIEF JUDGE BUMB: That's why I say it's a "big wow."
9 Let's find out. We'll figure it out.

10 Okay. Can we get started with the witness?

11 MR. SLATER: Judge, there is one thing that's not on
12 the agenda that will take about three minutes and I think will
13 be welcome news to the Court. If I could maybe --

14 CHIEF JUDGE BUMB: On the punitives, yeah. You have
15 two weeks to work out the punitive issue. Is that what you
16 want?

17 MR. SLATER: No. I was going to tell Your Honor that
18 Doug Tween is here, the attorney for VivaMed. I wanted to let
19 the Court know that we've settled with VivaMed.

20 CHIEF JUDGE BUMB: Anybody else? That's awesome.

21 MR. SLATER: We had agreed that we would tell Your
22 Honor at the conference a few days ago we've reached agreement.
23 We're working on the documents, but we thought Your Honor would
24 want to know. So...

25 CHIEF JUDGE BUMB: I applaud you. Thank you.

1 And who may I address?

2 MR. HONIK: Your Honor, I think the witness --

3 CHIEF JUDGE BUMB: Who is the attorney? Who is here?

4 MR. SLATER: I'm sorry. One second, Ruben. It's

5 Douglas Tween, who represents VivaMed in the claims which

6 related only to losartan. We've settled the economic loss

7 class action claims, and we've settled -- we're aware of one

8 personal injury case, that settled. There may be one other

9 case they're talking about, but we've resolved them.

10 CHIEF JUDGE BUMB: Counsel, just put your name on the
11 record.

12 MR. TWEEN: Douglas Tween, T-W-E-E-N, Linklaters LLP,
13 for VivaMed Life Sciences, Strides Pharma Science, Limited, and
14 Heritage Pharmaceuticals, Inc., d/b/a Abbott Pharmaceuticals,
15 Inc.

16 CHIEF JUDGE BUMB: And you concur with what
17 Mr. Slater has represented?

18 MR. TWEEN: I do, Your Honor.

19 CHIEF JUDGE BUMB: Okay. Thank you. And I applaud
20 you for your efforts.

21 MR. TWEEN: Thank you.

22 MR. SLATER: Thank you, Your Honor.

23 Are we starting the *Daubert* hearing with Dr. Conti
24 now? If you are, I just want to know so I can get out of the
25 way.

1 CHIEF JUDGE BUMB: Yes.

2 MR. SLATER: I'm going to just move, Your Honor,
3 because I'm not going to conduct that.

4 CHIEF JUDGE BUMB: Okay.

5 (Pause.)

6 MR. HONIK: Judge, may I from here?

7 CHIEF JUDGE BUMB: Yes. So let me just say this
8 before we get started.

9 Is the witness here?

10 MR. DAVIS: Yes.

11 CHIEF JUDGE BUMB: So I just, because we're going to
12 go all day, and as you folks know, I want to get as much
13 resolved as I can because tomorrow I cannot go all day. But I
14 would like, and I know there's a lot of helpers out there, I
15 would like to know the causes of action and I would like to
16 know the elements of the causes of action so that I can
17 continue this colloquy that we've been having. I think that
18 would be very helpful.

19 Okay. Dr. Conti, come forward, please.

20 (Witness took the stand.)

21 CHIEF JUDGE BUMB: John, can you administer the oath.

22 THE COURT REPORTER: Please raise your right hand.

23 *RENA CONTI, Ph.D., called as a witness for the*
24 *Plaintiffs, having been first duly sworn, was examined and*
25 *testified as follows:*

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1 THE COURT REPORTER: Please state and spell your name
2 for the record.

3 THE WITNESS: Rena Conti, R-E-N-A, C-O-N-T-I.

4 CHIEF JUDGE BUMB: Okay. Welcome. If you could
5 bring the microphone closer to you and speak into the
6 microphone. And there's water shortly.

7 Okay. Mr. Honik.

8 MR. HONIK: Thank you, Your Honor.

9 PLAINTIFFS' EVIDENCE

10 DIRECT EXAMINATION

11 BY MR. HONIK:

12 Q. Good morning, Professor.

13 A. Good morning.

14 Q. Your name has been the subject of considerable discussion
15 this morning. I'm delighted to be able to put you on the
16 stand.

17 Let me begin by asking you this: At my request, did
18 you undertake an economic analysis of the appropriate measure
19 of damages in connection with the manufacture and sale of
20 valsartan-containing drugs, or VCDs, that became the subject of
21 FDA recalls commencing in 2018?

22 A. Yes.

23 Q. And after determining the correct measure of such damages,
24 the exact methodology of which we'll discuss shortly in greater
25 detail, did you actually calculate the amount of those damages

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1 for both consumers and end payors, including third-party
2 payors, or TPPs?

3 A. Yes.

4 Q. In so doing, were you asked to assume certain facts
5 touching upon the liability related to the manufacture and sale
6 of those products?

7 A. Yes.

8 Q. Now, your opinions regarding the calculations and how you
9 arrived at them are contained within the several reports or
10 declarations that you've authored since the beginning of the
11 case, is that correct?

12 A. That's correct.

13 Q. I want to take a moment to provide or identify the four
14 reports that you've authored so that the record is clear on the
15 entirety of the work that you have done in this case.

16 The initial report or declaration was in
17 November 2021 in support of our class cert motion; is that
18 correct?

19 A. Correct.

20 Q. And very briefly, in that, you calculated, using a
21 methodology we'll discuss in a moment or so, damages as against
22 manufacturers and finished dose suppliers, all of them in this
23 case for all claims, all states, for all relevant times; is
24 that correct?

25 A. Correct.

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1 Q. And then subsequent to that, in March of 2022, you
2 supplemented that with an additional calculation of damages for
3 certain retailers whose data became available subsequently,
4 correct?

5 A. Correct.

6 Q. All right. Now, fast forward to February of 2023, you
7 prepared yet another report at that time on MSP, the class rep
8 in this case, and their specific damages, correct?

9 A. Correct.

10 Q. And I hasten to point out that was submitted and it is on
11 the ECF dated as of February 3, 2023, two days before this
12 Court certified the class. Do you remember that?

13 A. I do.

14 Q. All right. As a consequence, the MSP-specific damages
15 were calculated by you out of a belief that the bellwether MSP
16 trial could be either a class trial or an individual case; is
17 that correct?

18 A. That's correct.

19 Q. And then finally, in December of last year, 2023, you
20 prepared yet another supplemental report on class-wide TPP
21 damages that included some fairly recently supplied pharmacy
22 defendant sales data, correct?

23 A. That's correct.

24 Q. All right. And that now represents the totality of your
25 work in this case, correct?

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1 A. Correct.

2 Q. Is it true that in every instance, in authoring these
3 reports and arriving at your damage calculations, that you
4 applied the same methodology?

5 A. Yes.

6 Q. Now, among the assumptions that you were asked to make in
7 preparing these reports was the identity of the manufacturers
8 and sellers of these VCDs, including, among others, the three
9 manufacturer/seller defendants in the upcoming bellwether
10 trial, namely, ZHP, Teva, and Torrent; is that correct?

11 A. Correct.

12 Q. You assumed, did you not, that the relevant sales of these
13 VCDs occurred between January 1, 2012, and the dates of recall
14 for each of these three defendants, July 2018 in the case of
15 ZHP and Teva and August 2018 for Torrent; is that correct?

16 A. That's correct.

17 Q. Now, critically, you were asked to assume that the
18 at-issue VCDs were contaminated with nitrosamines in a manner
19 which rendered them adulterated, correct?

20 A. Correct.

21 Q. You made no independent evaluation of the liability part
22 of this case, correct?

23 A. Correct.

24 Q. Professor Conti, since earning your Ph.D. in economics
25 from Harvard in 2006, have you largely, if not entirely,

1 confined your work, research, teaching, writing, and consulting
2 in both the government and the private sectors to the economics
3 of the medical care industry?

4 A. Yes. My Ph.D. is in economics and health policy.

5 Q. And health policy?

6 A. Correct.

7 Q. Thank you.

8 Has your work examined the factors that determine
9 spending levels and trends in medical care, including
10 prescription drugs?

11 A. Yes.

12 Q. You described qualifications in your initial report dating
13 back to November 2021 that, quote, your principal research
14 focus is on the economics of the healthcare industry and the
15 markets in particular, evaluating factors that impact the
16 purchase and use of pharmaceuticals, including quality, pricing
17 and availability of the pharmaceutical, physician prescribing
18 behaviors and incentives, insurance coverage, and reimbursement
19 and regulation; is that correct?

20 A. Yes. My expertise is largely in the financing,
21 organization, and regulation of the pharmaceutical industry.
22 And specifically almost all of my research has focused on the
23 demand, the supply, and the pricing of prescription drugs.

24 Q. And has that been true for the -- well, since 2006 at the
25 least?

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1 A. Yes.

2 Q. In addition, in a resume that I'll mark before you leave
3 the stand, did you also indicate that you've testified on the
4 economics of prescription drugs in hearings held before the
5 U.S. Senate?

6 A. Yes.

7 Q. Before the U.S. House of Representatives?

8 A. Yes.

9 Q. Before the U.S. Food and Drug Administration?

10 A. Yes.

11 Q. Before the Federal Trade Commission?

12 A. Yes.

13 Q. And before numerous state legislative houses. Is that all
14 correct?

15 A. Yes. That's correct.

16 Q. Do you serve as the special government advisor or have you
17 served as a special government advisor to the Centers for
18 Medicare & Medicaid Services, or more commonly known as CMS?

19 A. Yes. I've done three separate tours of duty in
20 Washington. I have been named special economic advisor to the
21 Food and Drug Administration in the Office of Generic Drugs to
22 focus on drug quality and shortage concerns.

23 I've also served in the previous administration in
24 the office of -- the commissioner's office under Commissioner
25 Scott Gottlieb, focused on specifically shortage concerns and

1 the supply of generic drugs.

2 In addition, I just came out of Washington serving as
3 a special economic advisor to the Centers for Medicare &
4 Medicaid Services where specifically my focus was on Medicare
5 Part D and Part B, both the regulations and also thinking about
6 reforms to insurance coverage that would improve access for
7 seniors.

8 Q. Professor, were you the health economist appointed by the
9 State of New Jersey for its Drug Affordability Council?

10 A. Yes. I've just been named on the board of the
11 Affordability Council for the State of New Jersey. In
12 addition, I'm currently serving on a board, affordability for
13 sickle cell disease for the State of Illinois.

14 Q. Professor, suffice to say, you familiarized yourself and
15 worked extensively with the regulatory framework that allows
16 generic drugs to come to market in the U.S.?

17 A. Yes. Almost all of my work on prescription drugs has
18 focused on competition and specifically the market for generic
19 drugs. This, by definition, includes the regulation, the
20 financing, and the organization of how patients get access to
21 these drugs and how much they cost and also what are the
22 factors that drive prescription drug companies to enter into
23 the U.S. market and to make them.

24 Q. Professor Conti, what then, in economic terms, is the
25 significance of a generic drug being adulterated in coming to

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1 market?

2 A. It goes to the foundation of the U.S. pharmaceutical
3 industry as it currently exists. Specifically, a drug label
4 contains the totality of the drug's quality manufacturing, its
5 safety, its purity, and its efficacy. And it is that label
6 that serves as an attestation that this drug is what it says it
7 is; that it reflects, at least a hundred years, since 1906, the
8 rules and regulations that have been put in place to protect
9 the U.S. public from products that are -- that might be
10 adulterated.

11 Q. Are drugs which meet those requirements that you've just
12 articulated, namely, the legal requirement for safety and that
13 they have the quality, purity, identity, and strength that
14 they're represented to possess in their approved label, are
15 those drugs, from an economic perspective, able to be assigned
16 a non-zero economic value by consumers and insurers alike?

17 A. Yes.

18 Q. Conversely, again, from an economic perspective, can drugs
19 that are adulterated and thus fail to meet those legal
20 requirements that we've just articulated, can they be assigned
21 a non-zero economic value?

22 A. No, they cannot.

23 Q. Can you explain why that is?

24 A. Sure, of course.

25 Consumers may have demand for many things, and firms

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1 might be able to meet that demand by supplying products. But
2 there are regulations on what firms can provide to meet
3 consumer demand, and those regulations essentially set up a
4 rule of road that allows for demand to be met by supply. It's
5 only when demand is met by supply can a market price be set for
6 the product.

7 CHIEF JUDGE BUMB: So if it's the only drug on the
8 market and it's adulterated and the FDA says, well, you're
9 going to have to choose the risk, there would be a value to
10 that?

11 THE WITNESS: Only --

12 CHIEF JUDGE BUMB: Correct?

13 THE WITNESS: Only if the risk is disclosed. And
14 indeed, the foundation of our rules of essentially Congress
15 creating a market for these products is to fundamentally
16 assess, is to fundamentally recognize that there's asymmetric
17 information between consumers and physicians on one hand and
18 suppliers on the other.

19 Without rules of the road being set, you could
20 imagine that in a market that has so much asymmetric
21 information, you could imagine that some suppliers could cheat
22 and indeed engender kind of picking -- as an FDA rule, in FDA
23 language, they say "picking the pockets," but also engendering
24 the health of consumers by doing so.

25 CHIEF JUDGE BUMB: No, and I understand that.

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1 But I wanted to get back to your opinion that if a
2 drug is adulterated, it is assigned a non-zero economic value.
3 I think that I can take judicial notice of the fact that there
4 have been times in the course of the FDA's history where there
5 are drugs that perhaps are adulterated, but it is the only drug
6 on the market. And the FDA has disclosed that risk, and said,
7 well, you're going to have to pick which risk, you know, is --
8 is one you're willing to undertake.

9 In that scenario, is it still your opinion that it
10 would be assigned a non-zero economic value?

11 THE WITNESS: If the risk is disclosed, then, of
12 course, by definition, and the rules allow for supply, then
13 there would be an economic value that could be assigned. And,
14 in fact, the market price should again reflect that additional
15 information about the drug and it should be one indication of
16 the market value.

17 CHIEF JUDGE BUMB: And so how do you then conclude
18 that if the risk is disclosed, there is an economic value? How
19 do you square that with, they have no economic value?

20 THE WITNESS: Sure.

21 CHIEF JUDGE BUMB: It seems to me that in that --
22 that that is inconsistent, because if the risk is disclosed and
23 it has a value, it's inconsistent with saying that they have no
24 economic value if they're adulterated. Those two seem to not
25 be reconcilable to me.

1 THE WITNESS: So I completely disagree, and let me
2 tell you why.

3 CHIEF JUDGE BUMB: Okay.

4 THE WITNESS: Again, it is in the U.S. Congress'
5 interest to facilitate the pharmaceutical industry for patients
6 to have demand and for firms to be able to meet that demand.
7 The rules of the road require that the firms disclose what the
8 risks of that product are in their totality.

9 So the squaring is that in order to make this market,
10 allow supply to meet demand, the risks have to be disclosed,
11 then there could be a market, and then there can be a product.
12 Then products can enter into the U.S. course of trade, and then
13 a price can be assigned to that.

14 CHIEF JUDGE BUMB: Okay. And then just one last
15 question and then I'll let you go.

16 You agree with me, though, that you can only disclose
17 the risk if you know the risk?

18 THE WITNESS: Well, by definition, it is the firm's
19 responsibility, it's their obligation to know what the risks
20 are and to disclose them on their label to the U.S. population.

21 CHIEF JUDGE BUMB: Okay.

22 BY MR. HONIK:

23 Q. If I may, I'd like to unpack that a bit more with you,
24 Professor.

25 We've used two terms here seemingly synonymously,

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1 but, in fact, they're not. Risk -- risks can be associated
2 with any number of drugs that enter the marketplace. We all
3 know that, correct?

4 A. Correct.

5 Q. And your essential point in response to the Court's
6 question is that when those risks are revealed, consumers and
7 insurers alike can weigh the risk and determine its value to
8 them, correct? Yes or no?

9 A. Yes. If --

10 Q. By contrast, something that's adulterated is in a
11 different category, isn't it?

12 Isn't it true that the FDA prohibits by statute the
13 sale of adulterated drugs, whereas it does not prohibit by
14 statute or otherwise drugs that may carry a risk that's
15 revealed?

16 A. That's correct. And, again, it goes to the 1938 rules,
17 which acknowledge that fundamental to the sale of these
18 products and to having a U.S. prescription drug market was that
19 the firms -- was that quality was inherent to the product. And
20 indeed in this specific case, it is the FDA's perspective that
21 between 2012 and 2018 that no amount of nitrosamine
22 contamination was allowable into the U.S. market.

23 Q. Has the FDA ever said that a drug manufacturer can sell
24 adulterated VCDs?

25 A. No.

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1 Q. In fact, has the FDA ever permitted, in a hypothetical or
2 other situation, the sale of adulterated drugs into the U.S.
3 market?

4 A. No.

5 Q. So that the Judge's hypothetical about revealing the risk
6 associated with the adulteration can't happen in the real world
7 because the FDA wouldn't permit it to be sold at all, correct?

8 A. Correct. Correct.

9 Q. And just to carry this out --

10 CHIEF JUDGE BUMB: Well, I thought they did in this
11 case, didn't they? When there was a recall, they advised the
12 patients to go ahead and decide what the risk is.

13 MR. HONIK: There was a temporary threshold limit
14 permitted during a period of acute shortage in the marketplace.

15 CHIEF JUDGE BUMB: Yeah. So I think that -- I think,
16 you know, I think we have to be fair to what the record is
17 here.

18 MR. HONIK: I agree, Your Honor, but it's immutable.

19 BY MR. HONIK:

20 Q. Do you know the United States code that covers the
21 prescription against placing adulterated drugs into the U.S.
22 market?

23 A. Yes.

24 CHIEF JUDGE BUMB: No, I don't want to quarrel about
25 that. I think it's -- I think it's undisputable that the code

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1 says and FDA says you cannot market adulterated drugs. I don't
2 think anybody's going to dispute that, and we shouldn't spend a
3 whole lot of time on that.

4 MR. HONIK: Thank you, Judge.

5 CHIEF JUDGE BUMB: Okay. We really shouldn't. But I
6 do think that it's probative, and I don't think it's a fact
7 that should be ignored that it cannot be said in a vacuum that
8 at no time can adulterated drugs be sold.

9 Because in this case, the facts as I understand them
10 and the evidence will show that the FDA permitted it. That's
11 all I'm saying. So I think we have to be a little careful
12 about making these black-and-white statements.

13 Go ahead.

14 BY MR. HONIK:

15 Q. Nonetheless, professor, is the pharmaceutical
16 manufacturer's compliance with cGMP the foundation upon which
17 prescription drugs are sold and purchased in the U.S.?

18 A. Yes. Again, quality is foundational to the sale of these
19 products.

20 Q. And do you know whether these rules in any way benefit the
21 drug companies as well?

22 A. Of course they do. In fact, it was the pharmaceutical
23 industry that wanted these rules to be in place to protect them
24 from unscrupulous firms undercutting them and stealing market
25 share using drugs that potentially were contaminated and also

1 were cheaper that didn't meet the evidentiary standard.

2 Q. And so that the record is clear and we'll move on, the
3 prohibition in the United States Code that prohibits the sale
4 of adulterated drugs is found at 21 U.S.C. 331(a) through (c),
5 correct?

6 A. That's correct.

7 Q. And you're familiar with its operation, correct?

8 A. Correct.

9 Q. Are the oversight activities by U.S. regulators predicated
10 upon the accuracy of information produced by the manufacturers
11 and their ongoing assurances of the safety, quality, and
12 efficacy of their products?

13 A. Yes.

14 Q. Do the FDA rules reaffirm the ongoing nature of it in that
15 manufacturers have to provide ongoing assurance of the safety
16 and efficacy according to cGMP?

17 A. Yes.

18 Q. Does the FDA recognize the public's need to rely on
19 prescription drug manufacturers' ongoing compliance with those
20 regulatory requirements and manufacturers' representations of
21 such compliance?

22 A. Yes. Yes.

23 Q. As a consequence of this regulatory scheme and its
24 specific requirements, which we've now discussed, if a
25 prescription drug is available for sale in the U.S. market, do

1 consumers and payors alike from an economic perspective expect
2 these drugs to meet or exceed minimum safety and quality
3 standards?

4 A. Yes, by definition.

5 Q. Now, in determining that a drug is economically worthless
6 in the way you've just laid out, that is, where supply and
7 demand curves do not meet, does that mean that the drug in
8 question can't have or retain some therapeutic or clinical
9 value?

10 A. The drug may contain therapeutic value. It does not have
11 economic value. There is no legitimate supplier.

12 Q. Can you expand a bit on that difference in the way it's
13 impacted your economic damage modeling in this case?

14 CHIEF JUDGE BUMB: I didn't hear the last sentence.
15 The drug may contain therapeutic value? It does not have
16 economic value what?

17 THE WITNESS: It does not have economic value.
18 I'll -- let me just be -- let me explain.

19 So consumers may have -- may demand many different
20 types of products, but that doesn't mean in the U.S. market
21 that suppliers can supply all of the products that consumers
22 may demand.

23 In this model, consumers might view that these
24 products have some therapeutic value, but suppliers cannot
25 supply products that might have that therapeutic value and are

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1 contaminated and are adulterated. That is not allowed.

2 CHIEF JUDGE BUMB: Unless the FDA says so?

3 THE WITNESS: Unless the regulator says so, allows
4 the commerce to trade like that.

5 CHIEF JUDGE BUMB: And in cases where they have not
6 yet said that, do they have an economic value?

7 THE WITNESS: They have authority -- so the FDA has
8 authority to determine what is allowable to enter into the U.S.
9 course of trade for pharmaceutical products.

10 CHIEF JUDGE BUMB: And so when you say they have no
11 economic value, that begins when the FDA declares them
12 adulterated?

13 THE WITNESS: No. It begins when the FDA allows a
14 product to be on the market. By definition, each one of
15 generic manufacturers have to show to the FDA and annually
16 attest that the products are manufactured according to cGMP,
17 and are pure, safe, and efficacious. And they need to attest
18 that label as well.

19 So think of it this way: The FDA's allowance of that
20 market to exist occurs when the FDA approves the label that the
21 manufacturer states here is the circumstances in which this
22 product has been manufactured and here are the economic -- or
23 here are the clinical benefits that might be provided.

24 Every single year that that drug has been on the
25 market, the manufacturer has to attest that that label is

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1 accurate and that these products are not adulterated. So in
2 the course of trade, that allows for this market to clear.

3 CHIEF JUDGE BUMB: So it sounds like what you're
4 saying is unless and until the FDA declares them adulterated,
5 they have some economic value?

6 THE WITNESS: Unless and until -- well, it's
7 really -- it's on the manufacturer, actually, to inform the
8 Food and Drug Administration that there has been contamination
9 and adulteration. That's part of their obligations. And once
10 that occurs, there's a period of determination by the regulator
11 on whether and how to either shut down the market for these
12 products or to allow them and under what circumstances. And
13 indeed that is what happened in this case.

14 CHIEF JUDGE BUMB: And up until that point, they have
15 an economic value?

16 THE WITNESS: Yes.

17 BY MR. HONIK:

18 Q. Professor Conti, let me ask you the question this way.
19 Let me get at it this way. Between 2012 and 2018, did the FDA
20 ever express or permit the introduction of
21 nitrosamine-contaminated ARBs in the United States?

22 A. No.

23 Q. And to your knowledge, it was impermissible to have the
24 nitrosamine-contaminated ARB sold in the United States during
25 that period, correct?

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1 A. Correct. During the period that I was assessing damages,
2 it was impermissible. The acceptable level was zero.

3 Q. Okay. And so the fact, the very fact of its sale has an
4 economic impact in terms of its value, correct?

5 A. Correct. You can think of this, again, from the FDA's
6 very colorful language, these are manufacturers that are
7 picking the pocket of American consumers and payors by selling
8 products into the market that should not have been.

9 Q. And during the same period in time, that is, from 2012 to
10 2018, there were non-contaminated, non-nitrosamine-containing
11 ARBs that were in the marketplace competing with these
12 contaminated or adulterated drugs, correct?

13 A. Of course.

14 Q. And those had value, economically speaking, and under
15 your -- or in your opinion, the others could not economically
16 because of the prescription by law, correct?

17 A. Correct.

18 Q. Now, let me hand you, if I may, your 2021 report.

19 Thank you.

20 MR. HONIK: Your Honor, may I approach?

21 CHIEF JUDGE BUMB: Yes.

22 BY MR. HONIK:

23 Q. Professor Conti, this is your initial report, the one
24 that's supported -- may I, Your Honor?

25 CHIEF JUDGE BUMB: Yes.

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1 MS. BROWN: Do you have a copy?

2 MR. HONIK: Do you have another one?

3 MS. BROWN: Thank you.

4 MR. HONIK: Thank you.

5 MS. BROWN: You can take mine. Thanks.

6 BY MR. HONIK:

7 Q. This is your expert declaration dated November of
8 2021, in which, as we've already established, you had prepared
9 calculations showing damages as against all the manufacturer
10 and finished dose suppliers as to all claims during all
11 relevant periods by state, correct?

12 A. Correct.

13 Q. And I've tabbed for you and the Court the pages that
14 correspond to the calculations that you arrived at for each of
15 the defendants. Do you see the tabs on there?

16 A. I do. This print is small, so apologies. I'm going to
17 put my glasses on.

18 Q. Well, let's go slow just so the record is clear and
19 everybody can follow. At Appendix C2, Cat 2, you provide
20 damage calculations for express warranty by defendant and by
21 state, correct?

22 A. Correct.

23 Q. And at Appendix E2, Edward 2, you provide similar
24 calculations by defendant and state as to common law fraud,
25 correct?

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1 A. Correct.

2 Q. And at Appendix F, as in Frank, 2, you calculate damages
3 again by defendant and state for Consumer Protection Law,
4 correct?

5 A. Correct.

6 Q. And the formula, I don't think there's much dispute about
7 this, is you determined the price at the point of sale and the
8 quantity at the point of sale, correct?

9 A. Correct.

10 Q. Second half step back. What is the significance of the
11 point of sale in your damage analysis?

12 A. Sure.

13 So it is at the pharmacy counter where patients are
14 picking up a dispensed product and potentially handing over
15 cash, if they have some sort of out-of-pocket cost, but also
16 that that claim is being adjudicated by the pharmacy. And the
17 pharmacy is calculating the amount that the consumer is going
18 to have to pay, if any, and the insurer is going to have to
19 pay. That is the point of the transaction from an economic
20 perspective.

21 It is that exchange of goods, money, if you will, for
22 the product where the benefit-of-the-bargain is struck and
23 where -- and it's that market price, what the patient pays and
24 what the insurer pays, that is the basis of economic damages in
25 this setting.

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1 Q. And clearly, I think we all understand that when that
2 adjudication -- well, let me back up.

3 Can the -- does the pharmacist release the valsartan
4 to the patient unless that adjudication occurs?

5 A. No.

6 Q. So the pharmacist, if I've understood you, is assured that
7 on the one hand they're getting the consumer payment, it may be
8 cash, it may be a credit card?

9 A. Uh-huh.

10 Q. And a promise to pay, are they not, from the insurer or
11 the TPP, correct?

12 A. Yes. I mean, from my perspective, it's an obligation to
13 pay by the insurer and by the patient for that product.

14 In addition, it's very important that, again, the
15 label is the promise by the manufacturer to the patient that
16 what this thing is is what it says it is on its label.

17 And, in fact, when you go -- when you leave a
18 pharmacy with a prescription drug, you will notice that
19 patients get that label stapled to their -- to their
20 prescription in order to reinforce here is what you have
21 bought, and this is what you as the manufacturer have promised
22 the consumer and to the payor what you have received.

23 Q. And that label from 2012 to 2018 never once revealed that
24 there was nitrosamine or any carcinogen in these VCDs, did it?

25 A. Correct. During the period of damages, it was not

1 revealed.

2 Q. The Judge -- the Court has alluded to certain allowances
3 by the FDA after the recall for certain of these drugs at
4 certain levels. Were the manufacturers required to test and
5 reveal the levels?

6 A. They were. And the issue that I wanted to raise with you
7 is that there's a difference between drugs that already exist
8 in the normal class of trade and drugs that could enter the
9 market with contamination. What the FDA was trying to address
10 is that there are going to be drugs already delivered to
11 pharmacies all across America. There are 50,000 pharmacies all
12 across America. And that recall was going to take time to
13 gather all of the contaminated products.

14 And so essentially what they were allowing was that,
15 listen, we know that there are going to be products that are
16 going to be already entered into the normal class of trade, and
17 we're going to warn people that if you're going to buy these
18 products at the pharmacy counter or, physician, if you're going
19 to recommend these products, you should know that they are
20 contaminated.

21 Q. Professor Conti, how did you arrive at the price and the
22 quantity for the calculations that we are looking at in these
23 appendices?

24 A. I used the gold standard employed by the industry for the
25 past 60 years to evaluate the sales, quantities, and prices of

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1 prescription drugs in the pharmacy trade.

2 Q. And what's the name of the dataset that you relied upon
3 for that purpose?

4 A. It goes by a number of names because there's been a number
5 of mergers and acquisitions of the companies, but the dataset
6 specifically I used was IQVIA Xponent data.

7 Q. And why do you consider IQVIA Xponent data reliable for
8 use in calculating damages in this case? And if you will,
9 detail how the data is collected, the size and scope and its
10 use.

11 A. Sure.

12 There are 9 billion, with a B, prescriptions
13 dispensed into the U.S. market every year. IQVIA goes out and
14 creates a census of the 50,000 pharmacies in the United States
15 selling these products. It also surveys all of the
16 manufacturers selling their products -- I think there are over
17 10,000 different prescription drugs sold in the United States
18 currently -- and asks both the pharmacies and the
19 manufacturers, what do you sell and how much did you sell it
20 for?

21 They then "hoover" up all of that data across the
22 entire nation and harmonize it. They clean it. They make
23 standard fields for quantities, for prices, for sales for every
24 single drug sold, and then they do a fair amount of cleaning
25 with that information, and then they finally start to analyze

1 it. They look for potential discrepancies in, let's say, what
2 the manufacturer says that they are selling into the U.S. and
3 what the pharmacies are saying that they're actually selling
4 into the U.S. They look for those sort of discrepancies and
5 seek to try to correct them, if you will.

6 And then finally they create a clean dataset that is
7 sold into the U.S. market, and their biggest customers are
8 prescription drug companies themselves that are trying to
9 assess what is the market for these products both in a given
10 point in time but also over time.

11 One other thing I should say is that the way that --
12 the reason that IQVIA can do this is because the U.S.
13 pharmaceutical market is a closed system. Under Food, Drug,
14 and Cosmetic Act, there has been rules called track and trace
15 where every single dispensed product in America and actually
16 every single drug sold into the wholesale class of trade is
17 literally barcoded. And so they can follow it all the way
18 through the system from the warehouse where the manufacturer
19 has finished that dose and sold it into the U.S. class of trade
20 all the way to the pharmacy that takes possession of that drug
21 and finally to the actual individual patient that is picking
22 that product up from the pharmacy.

23 Q. And so as a result of this tracking and traceable --
24 traceability that you've described, can we know the patient who
25 picks up the drug?

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1 A. Absolutely.

2 Q. Can we know the quantity that was in the prescription
3 picked up?

4 A. Yes.

5 Q. Do we know the price that the consumer as well as the
6 consumer's insurer paid?

7 A. Yes.

8 Q. Do we know as well when the insurer paid it and where the
9 insurer paid it?

10 A. Correct. There is a --

11 Q. Do we know the amount the insurer paid?

12 A. Yes. There is a full and complete record. It is uniquely
13 identified by unique codes.

14 Q. And even if the payment is somewhat circuitous going
15 through potentially a PBM or some other agent on behalf of the
16 insurer, are those facts knowable?

17 A. Yes.

18 Q. Now, you mentioned there are some 9 billion prescriptions
19 annually in the United States. What percentage of those
20 9 billion are captured in the IQVIA dataset that you used in
21 this case?

22 A. So across all drugs sold in the United States, their
23 census is 93 percent. We believe their census is higher for
24 small molecule drugs, such as the ones at issue here. IQVIA
25 has a little bit of blindness in drugs that are -- there's a

1 little bit of "missingness" in drugs that are dispensed in the
2 inpatient setting because of how those products are purchased
3 and tracked to patients but not for these particular drugs
4 where they are largely dispensed to patients in the pharmacy
5 counter.

6 Q. But in using IQVIA for this case for VCDs in question,
7 were you satisfied that you were picking up 93 percent or north
8 of 93 percent of all drug sales during the relevant class
9 period?

10 A. Yes. You should think of these data as being a census of
11 the prescription drugs at issue in this case being sold into
12 the U.S. market.

13 Q. You --

14 A. And paid for in the U.S. market.

15 Q. You've used the term "census" a couple of times. Is there
16 a difference definitionally in economics or statistics that
17 relate to economics between census and sample?

18 A. Yes. A census is when a researcher or government agency
19 literally goes and tries and ascertains economic features of
20 whatever the phenomena is of interest for every single person
21 or firm that is participating in the market. Think of the U.S.
22 census as a census, a true census.

23 A sample is different. A sample is when you go out
24 and ask a handful of people or a handful of firms what they are
25 doing, what the economic phenomena is of interest. They are

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1 fundamentally different concepts.

2 Q. By the way, you mentioned industry, that is,
3 pharmaceutical industry's use of IQVIA. Is it used in
4 research?

5 A. Yes. So IQVIA does sell their data largely to
6 pharmaceutical firms for market intelligence, but they also
7 will enter into contracts with researchers, such as myself, and
8 with government agencies, such as the Centers for Medicare &
9 Medicaid Services. The Food and Drug Administration uses IQVIA
10 data. There are various other government agencies that rely on
11 the data to assess market sales and quantity and prices of
12 prescription drugs sold in the United States.

13 Again, it is the census. It is the one thing that
14 we -- it is the data that allows us to ascertain all
15 prescription drugs sold in the United States across payor,
16 across drug, across manufacturer within state.

17 Q. And implicit in your last response, is it therefore relied
18 upon to establish U.S. drug policy?

19 A. Absolutely. In every -- in my role as a researcher, in my
20 role as a special government advisor, and in my interactions
21 with government agencies throughout the federal government,
22 whether it be in health and human services or in other parts of
23 the agency, IQVIA is considered to be a gold standard for
24 evaluating the market for prescription drugs in the United
25 States.

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1 Q. Professor Conti, you were, in fact, the expert retained in
2 the *Blue Cross Blue Shield/GSK* case about which the Court heard
3 earlier in the Eastern District of Pennsylvania, were you not?

4 A. Yes.

5 Q. Did you use IQVIA data there to model damages?

6 A. Yes.

7 Q. Now, did you model damages in this case employing a subset
8 of other data that came into your possession?

9 A. Yes.

10 So it is important for scientific inquiry to be
11 thorough and to evaluate all of the financing, organization,
12 and regulations that govern a particular economic phenomena of
13 study.

14 In the course of doing my work in this case, I
15 evaluated a number of other datasets that were given to me to
16 assess their reliability and to judge it against the gold
17 standard, which is IQVIA data.

18 Q. And, in particular, did you analyze a data subset
19 consisting of some nine big box or large grocery-store-type
20 drug dispensers in the country?

21 A. I did.

22 Q. And so the Court has some relative idea of how much was
23 captured in that data in comparison to some 9 billion that you
24 mentioned earlier, give us a sense of the number of
25 prescriptions captured in this smaller data subset that you

1 analyzed.

2 A. So for the drugs at issue, it was quite incomplete. To
3 give you an example, the -- the -- some of the drugs had only
4 a -- the sample contained only 14 percent relative to the IQVIA
5 census, whereas some of the drugs at issue were more
6 representative in the sample than in comparison to the IQVIA
7 data.

8 Q. So let's unpack that a little bit. When you say that in
9 this subset that you looked at in the sample seeing only
10 14 percent, do you mean 14 percent of total sales in question?

11 A. Correct, of total quantity sold.

12 Q. And that would be in contrast to the 93 percent or higher
13 captured in IQVIA?

14 A. Correct.

15 Q. Is that fair?

16 A. Correct.

17 Q. Did you observe whether or not there was a convergence in
18 price point, the larger the share was or the larger the
19 percentage, reflected in the smaller subset?

20 So in other words, looking at the subset that had
21 roughly 70 percent, did that more closely approximate the
22 pricing that you saw in IQVIA in comparison to the capture at
23 14 or 17 percent?

24 A. Yes, of course. So the economic principle here is that as
25 a sample converges on the census, the true estimate or the

1 estimate in the sample converges on the true estimate in the
2 census.

3 Q. When you --

4 CHIEF JUDGE BUMB: Counsel, I don't think there's a
5 dispute about this. I think the dispute really is her
6 conclusion that they were rendered worthless and the unjust
7 enrichment theory. So to the extent you can hone your
8 examination as to those two objections, I would appreciate it.

9 MR. HONIK: I will, Your Honor.

10 And for the benefit of the Court, the reason we're
11 bringing this up is that this was very specifically in the
12 *Daubert* motion that the defendants filed; that there was some
13 impropriety in using IQVIA as opposed to pricing that was
14 revealed in the smaller --

15 CHIEF JUDGE BUMB: So my ruling will be -- I'll
16 shortcut it -- that goes to the weight of the opinion. It does
17 not go to reliability.

18 MR. HONIK: Thank you, Your Honor. I appreciate
19 that. I appreciate that.

20 BY MR. HONIK:

21 Q. Are you familiar in the drug industry with the use of
22 rebates and post-sale offsets?

23 A. Well, there are a number of different changes to the list
24 price of the drug in the U.S. There are discounts that are
25 applied at the point of sale. Those are already reflected in

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1 IQVIA data. There are also post-sale adjustments, and they can
2 include rebates largely and then a handful of other adjustments
3 as well.

4 Those rebates are usually paid by -- or those
5 adjustments are paid by the manufacturer to either the insurer,
6 to the patient itself or their self, or to the pharmacy.

7 Q. With respect to post-sale offsets of the kind that you
8 just described, you were certainly aware of them, as you've
9 just stated. Did you calculate them and reduce the point of
10 sale harm?

11 A. Again, the discounts that exist in the U.S. market and
12 that are part of the dispensed prescription price are already
13 in the IQVIA data. It's one of the advantages of using the
14 IQVIA data.

15 The rebates that might be available from
16 manufacturers to insurers, other parts of the trade, were not
17 captured, and that's because generic drug manufacturers do not
18 provide rebates to consumers or to third-party payors.

19 Q. So, professor, if we turn now to your actual calculations
20 of TPP damages, would a fact finder be able to use the
21 appendices that we went through earlier, the three in
22 particular, which show the calculated damages that we discussed
23 by defendant, by state, and by claim to answer damage questions
24 about the three defendants in the upcoming bellwether trial?

25 A. Yes.

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1 Q. And let me show you, if I may --

2 MR. HONIK: Your Honor, may I approach again?

3 CHIEF JUDGE BUMB: Yes.

4 THE WITNESS: Thank you. Thank you for the larger
5 print.

6 BY MR. HONIK:

7 Q. Professor Conti, this is a composite exhibit, basically an
8 Excel spreadsheet. Do you have it in front of you?

9 A. I do.

10 Q. And the composite exhibit reflects the claims asserted
11 against the bellwether defendants, namely, ZHP, Teva, and
12 Torrent, by state groupings that have been certified by this
13 Court and assigned for the upcoming trial and by claim, namely,
14 express warranty, fraud, and consumer protection.

15 Did you at my request take the values from your
16 appendices and then input the specific damage as they would
17 relate to this upcoming trial?

18 A. Yes, correct. All of the damages that are in my opening
19 report, attachment C2, E2, and F2, are just summarized in this
20 document.

21 Q. And the composite exhibit consists of three different
22 tabs, if you will, from an Excel spreadsheet as to each of the
23 defendants, correct?

24 A. Correct.

25 Q. And there are no unjust enrichment calculations in this

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1 exhibit, correct?

2 A. Correct.

3 Q. Now, in much the same way, based on your testimony,
4 developed testimony, obviously, could a fact finder look to
5 your appendices and the calculations there, the basis for it,
6 and subject, of course, to the Court's instructions, then take
7 the damages from one and put it on a verdict sheet similar to
8 the composite exhibit I've placed in front of you?

9 A. Yes.

10 Q. And can -- if you would, let's just take a minute and look
11 at a couple of examples so that we understand some concepts
12 that are here.

13 So with respect to ZHP damages, for example, if we
14 look at the very first state alphabetically, we see Alabama,
15 correct?

16 A. Correct.

17 Q. And the first column for damages would be under express
18 warranty, and there's a non-zero value there, correct?

19 A. Correct.

20 Q. And you see where it says common law fraud NA?

21 A. Yes.

22 Q. Okay. And that would correspond to the unavailability of
23 a particular claim in a particular state, correct?

24 A. Correct.

25 Q. Same thing with respect to Alabama, the example we're

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1 using, for Consumer Protection Law, correct?

2 A. Correct.

3 Q. And then you've got a column that says "deduplicated state
4 total." Do you see that?

5 A. Yes.

6 Q. For states and claims, like, for example, Florida, which
7 has values for both -- for all three, express warranty, common
8 law fraud, and Consumer Protection Law, what do you mean by a
9 deduplicated state total?

10 A. Sure.

11 So as you can see, some of these states have laws
12 that allow for claims of express warranty but not the others,
13 while some of the states have allowed for claims of express
14 warranty and some of the others.

15 All the deduplicated state total does is say, okay,
16 you only get credit or only are -- were only a sum of damages
17 for you for one of the damage categories, not all.

18 Q. So in plain English, there's no double-dipping here,
19 correct?

20 A. There's no double counting here, correct.

21 Q. And --

22 CHIEF JUDGE BUMB: And am I correct that this is
23 not -- that you are not making an opinion as to whether or not
24 the elements of each of these theories has been satisfied?

25 THE WITNESS: Correct.

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1 BY MR. HONIK:

2 Q. Right. You have no opinions one way or the other about
3 any of the elements of the liability in this case, correct?

4 A. Correct.

5 Q. You've simply calculated the damages?

6 A. Correct.

7 MR. HONIK: Your Honor, if I may, the last thing for
8 the benefit of the Court.

9 CHIEF JUDGE BUMB: Okay.

10 MR. HONIK: I'd like to show Professor Conti and have
11 her confirm that this is her most recent CV.

12 BY MR. HONIK:

13 Q. Dr. Conti, is this your most recent biography and CV?

14 A. I think I've had -- so the address is accurate, employment
15 is accurate.

16 Q. It may help you to know that your assistant sent it to me
17 this week.

18 A. Yeah. Thank you.

19 I think there are a handful of additional
20 publications that are not listed here. So, for example, I just
21 published a paper in the New England Journal of Medicine on the
22 market for prescription drugs that's not listed here.

23 But it looks pretty complete.

24 Q. You have in excess of a hundred publications in your area
25 of expertise, correct?

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1 A. I do.

2 Q. And we may be missing a few?

3 A. Yes.

4 MR. HONIK: Thank you. That's it, Your Honor.

5 CHIEF JUDGE BUMB: Cross. We'll go till about 12:30.

6 MS. BROWN: Your Honor, may I be heard just a minute
7 before we start?

8 CHIEF JUDGE BUMB: Okay.

9 MS. BROWN: The bulk of what I intended to talk to
10 Dr. Conti about today is actually an issue I thought I heard
11 the Court just rule on, so I want to be mindful about
12 retreading ground if the Court has ruled.

13 CHIEF JUDGE BUMB: Well, I think that she's testified
14 that this is the standard in the industry, this is what she
15 uses, and to the extent that the defendants quarrel with the
16 IQVIA analysis, that goes to the weight.

17 MS. BROWN: I understand the Court's position.

18 I would push back just a little bit, if I could. I
19 think the new advisory committee notes from December of 2023
20 about Rule 702 make clear that it is the application of the
21 methodology that is, of course, as this Court well knows,
22 within the purview of the Court's gatekeeping role.

23 And I would submit to the Court that in this instance
24 we have an issue with the reliability of the IQVIA Xponent
25 data. And here Dr. Conti actually did two different damage

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1 calculations, Your Honor, and they differ by one billion. And
2 I believe that the difference is because, and we argued in our
3 papers, the unreliability of using IQVIA data, which is not
4 transaction data, Your Honor, it's an aggregate. It's based on
5 a survey. There's a number of different issues with that.

6 And so I don't think, Your Honor, in this instance it
7 is a weight issue. It's a reliability issue that I think the
8 advisory committee note makes clear that at this point is
9 within the gatekeeping 702.

10 And so, Your Honor, if the Court would permit me, I
11 would like to --

12 CHIEF JUDGE BUMB: If you want to make your record,
13 make your record. I don't know. I think it goes to the weight
14 of the evidence.

15 Can I just ask a question? You just assumed that the
16 entire data were all losses, right? You didn't make a
17 calculation as to -- you just assumed there was no economic --
18 they were all economic losses?

19 Like, I didn't hear any questioning about how you get
20 to these numbers other than you just -- you looked at the data,
21 you saw how many prescriptions were written, and you assumed
22 that they all had no value, right?

23 THE WITNESS: Yes, that's correct.

24 CHIEF JUDGE BUMB: You just made that assumption?

25 THE WITNESS: That's correct, based on the -- based

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1 on what I was asked to assume.

2 CHIEF JUDGE BUMB: Yeah. You were told let's just
3 assume that these -- that the drug has no value, and you were
4 told to go back and see how much -- how many prescriptions
5 were --

6 MR. HONIK: Your Honor, respectfully, we did not ask
7 her to assume it had no value. We asked her to assume one
8 thing.

9 CHIEF JUDGE BUMB: What?

10 MR. HONIK: That the drugs were adulterated. And we
11 asked her, based on her expertise, what is the economic
12 significance of the adulterated drug?

13 CHIEF JUDGE BUMB: But then how did she --

14 MR. HONIK: She then opined, under 21 U.S.C., 331,
15 those drugs are impermissibly -- are not permitted to be in the
16 U.S. market. She then explained that there needs to be a
17 convergence of a supply-and-demand chain from an economic
18 standpoint. So there is a foundation, and she made no
19 assumption of zero value. She arrived at zero value based on
20 an economist's very sound foundation. So there is a difference
21 here.

22 CHIEF JUDGE BUMB: Well, unless -- unless I was
23 missing something, her testimony -- this is how I heard her
24 testimony. And I don't know how -- this is how I heard her
25 testimony, which is, a drug that has been deemed adulterated by

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1 the FDA has no economic value, and up until that point, an
2 argument can be made that it has an economic value.

3 The record in this case reflects that from day one it
4 was not recalled. And so wherein, in that range, the drug has
5 value or doesn't have value is disputed, and that's what the
6 jury will have to decide. That's how I heard the testimony.

7 And so whether it was an assumption that they had no
8 value from day one when they were put into the market, it
9 doesn't comport with the testimony I heard today. I heard
10 something entirely different. But we get back to the same
11 conversation that I have been having, which is the dispute is
12 going to center on whether or not they had a value, the drug
13 had a value.

14 I did not hear this witness say that they have no
15 value from the minute -- from the minute they were
16 manufactured. I did not hear her say that.

17 MR. HONIK: Your Honor, you're correct in part, if I
18 may.

19 It's on us to demonstrate adulteration in 2012.
20 We're going to do that.

21 CHIEF JUDGE BUMB: Okay.

22 MR. HONIK: We're going to show to this jury through
23 extremely competent, extensive testimony from defendants and
24 others that by reason of how they manufactured these drugs,
25 that they were, in fact, adulterated. That is, if I may --

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1 CHIEF JUDGE BUMB: I understand that.

2 MR. HONIK: That they contained nitrosamine --

3 CHIEF JUDGE BUMB: Right.

4 MR. HONIK: -- from 2012 all the way forward.

5 CHIEF JUDGE BUMB: Right.

6 MR. HONIK: So as a matter of fact, they were
7 adulterated.

8 And so what Professor Conti did -- we asked her, what
9 is the significance of that fact -- once we establish it,
10 obviously -- that the drugs were adulterated within the meaning
11 of the FDA regulations in 21 U.S.C.? What is the economic
12 significance of that?

13 And her response is, they have zero value because
14 they can't be placed into the stream of commerce. And as an
15 economist, that imputes that there's no supply and demand curve
16 that meets. No equilibrium of pricing can be established.

17 CHIEF JUDGE BUMB: And I think that that --

18 MR. HONIK: So on her own, through her economic
19 analysis, the ascribed value, remember, benefit-of-the-bargain,
20 what was the objective value of the drug at the time it was
21 dispensed and what was paid. That became the delta for
22 damages.

23 So it's -- there are at least these couple of
24 important steps, and we concede absolutely that we've got to
25 demonstrate adulteration.

1 CHIEF JUDGE BUMB: And what I heard the testimony to
2 be is that when a drug is -- I will be generally speaking -- is
3 that when a drug is recalled, it has no economic value. But up
4 until that point, there is an economic value.

5 The witness assumed in her analysis that there is --
6 there should be ascribed no economic value to a drug where the
7 evidence will show that it was adulterated from day one. That
8 will then be, and that's an assumption she made and it's an
9 assumption she is more than permitted to assume. It's a
10 hypothetical and she's presuming it. She's presuming that
11 these drugs were adulterated from day one and had no economic
12 value.

13 She will -- she's not qualified to say, it seems to
14 me, in a vacuum that they had no economic value because she
15 herself has testified today that up until the point that
16 they're recalled, they have some economic value.

17 MR. HONIK: I --

18 CHIEF JUDGE BUMB: What that value is, whether
19 they're worthless from day one or not, is up to the jury to
20 decide.

21 MR. HONIK: Respectfully, Judge, I don't think
22 Professor Conti testified that way at all.

23 CHIEF JUDGE BUMB: I specifically said to her up
24 until the point --

25 MR. HONIK: If I may, there is a difference between a

1 drug that contains a risk and a drug that is adulterated, and
2 she distinguished between the two. She said that if a drug has
3 a revealed risk, that has -- and can be assigned a value, and
4 the reason for that is that the asymmetry between what a
5 consumer knows and what a drug manufacturer knows is
6 alleviated.

7 But when that doesn't exist and when there is a
8 contamination that is not revealed, i.e., it's adulterated, it
9 can never have a value even before recall.

10 The trigger here is not recall. It's not when the
11 FDA -- and I'm going to find, before the day's over, Judge
12 Kugler absolutely addressed this point.

13 CHIEF JUDGE BUMB: That's not what she said.

14 THE WITNESS: If -- respectfully --

15 CHIEF JUDGE BUMB: It's -- no, no.

16 THE WITNESS: Respectfully, that is not -- that is
17 not what I said. That is not my testimony.

18 Again, there is no --

19 CHIEF JUDGE BUMB: Lunch break.

20 THE COURTROOM DEPUTY: All rise.

21 CHIEF JUDGE BUMB: We'll see you back in 45 minutes.

22 (Recess was taken at 12:21 p.m. until 1:45 p.m.)

23 THE COURTROOM DEPUTY: All rise.

24 CHIEF JUDGE BUMB: Okay. Sorry for the delay. You
25 can have a seat. Thank you.

1 Is Dr. Conti here?

2 Resume the stand, please.

3 (Witness resumed the stand.)

4 CHIEF JUDGE BUMB: Okay. Please remember you're
5 still under oath.

6 Cross.

7 MS. BROWN: Yes, Your Honor.

8 And, Your Honor, we certainly heard the Court on the
9 IQVIA issue, and so we'll just rest on the argument we made in
10 the papers, understanding that the Court views that as an issue
11 of weight.

12 CHIEF JUDGE BUMB: Okay.

13 MS. BROWN: And if I could, Your Honor, proceed with
14 just a few questions on another topic that we briefed, which
15 was the "fit," Your Honor, whether or not the damages model
16 particularly as it relates to the state damages fits the theory
17 of liability and how the classes were certified.

18 May I proceed with just a few questions on that?

19 CHIEF JUDGE BUMB: Yes. Yes.

20 MS. BROWN: Thank you.

21 CROSS-EXAMINATION

22 BY MS. BROWN:

23 Q. Good afternoon, Dr. Conti.

24 A. Good afternoon.

25 Q. How are you?

1 A. I'm great. How are you?

2 Q. Good.

3 A couple of questions for you on this exhibit that
4 counsel marked with your state-specific calculations.

5 A. Just give me a second, please.

6 Q. Sure.

7 And if it's helpful, I can approach with my copy,
8 Dr. Conti.

9 A. I've got it. Thank you.

10 Q. Okay. Perfect.

11 A. If you could just give me one second so that I have the
12 reference as well.

13 Q. Sure.

14 A. Thank you.

15 Okay.

16 Q. You're all set?

17 A. Yes.

18 Q. Okay. Great.

19 When we look at this exhibit that counsel marked, it
20 contains your calculations of damages broken down by state and
21 by damages category, correct, Doctor?

22 A. Yes.

23 Q. Okay.

24 A. Professor.

25 Q. I'm sorry?

1 A. Professor.

2 Q. Professor.

3 A. Yes. I'm not a physician.

4 Q. Sure.

5 And I understand, Professor, that this state data
6 comes from the IQVIA data, correct?

7 A. I don't know what you mean by "deck"?

8 Q. Excuse me?

9 A. What do you mean by "deck"?

10 Q. Sure.

11 A. Do you mean data?

12 Q. Data. I say data. Do you say data?

13 A. You said "deck." That's what I heard.

14 Q. Oh, sorry. I said the word "data."

15 Can you hear me?

16 A. I can now, yes.

17 Q. Okay. The state damages data comes from IQVIA data,
18 correct?

19 A. Correct.

20 Q. Okay. And that data is based on, you told us at your
21 deposition, the state of the pharmacy where the transaction for
22 the medicine occurred, correct?

23 A. Yes.

24 Q. Okay. But in a different proceeding, you testified that
25 IQVIA data is based on the state where the prescriber writes

1 the prescription.

2 A. Correct.

3 Q. Do you know that?

4 A. It's the same.

5 Q. Well, the state where the prescriber is, is not
6 necessarily the state where the consumer goes to fill the
7 prescription, correct?

8 A. No, that's not correct. Indeed, there has been a fair
9 amount of research on this. Healthcare is a local good where
10 people go to the doctor in their local community and go to
11 their pharmacy in their local community just like they go to
12 their hospital in their local community.

13 CHIEF JUDGE BUMB: Well, you just made the assumption
14 that they were both the same. I mean, it doesn't always happen
15 in that case, but for purposes of your report, you assumed that
16 the state where the prescriber was is the same where it was
17 filled; you just made that assumption?

18 THE WITNESS: Right. So --

19 CHIEF JUDGE BUMB: Okay.

20 THE WITNESS: I mean, generally, the state of the
21 pharmacy and the state of the prescriber are the same.

22 CHIEF JUDGE BUMB: And that's --

23 THE WITNESS: But, yes, there can be discrepancies as
24 well.

25 CHIEF JUDGE BUMB: Okay. So it was an assumption

1 that was made. Okay.

2 MS. BROWN: Thank you, Your Honor.

3 BY MS. BROWN:

4 Q. And one of the things that you've actually written about
5 is that the location of a pharmacy where a prescription is
6 filled might be different from the location where a person or a
7 patient lives, right?

8 A. So, again, healthcare consumption, in the U.S., the most
9 commonly consumed medical care product are pharmaceuticals, and
10 healthcare consumption generally of medical care goods are a
11 local concern. In other words, patients go to their local
12 doctor, patients go to their local pharmacy for care.

13 Can people cross the border into different
14 communities to fill a prescription? Absolutely. But generally
15 that is contained within their state.

16 Q. And one of the things you would agree with is that in many
17 urban and rural areas, the location of a pharmacy where a
18 prescription is filled may be discordant with the patient's
19 residence, correct?

20 A. But, again, all -- all within the same state.

21 In other words, I lived in the south side of Chicago
22 when I was faculty at the University of Chicago for 15 years.
23 I would get my prescription filled in multiple pharmacies, some
24 of which were in the south side of Chicago and some of which
25 were in the north side of Chicago.

1 CHIEF JUDGE BUMB: Is this material? It seemed to be
2 a little nitpicky. Can we just assume that what --

3 MS. BROWN: Yeah, I think it is. Well, I think
4 here's the issue, Your Honor, and I'll move on.

5 CHIEF JUDGE BUMB: Yeah.

6 MS. BROWN: Whether it -- and I don't think Dr. Conti
7 knows whether it's the prescriber or whether it's the pharmacy.
8 What it's not is the state where the TPP paid. And that was
9 what Judge Kugler identified as a mismatch. And that's the
10 area of questioning I just want to ask a few questions on and
11 argue to the Court that we have a "fit" problem as a result of
12 that.

13 CHIEF JUDGE BUMB: Well, assume we do, then how does
14 that -- I mean, so do you just throw the entire opinion out?

15 MS. BROWN: Well, what Judge Kugler said, Your Honor,
16 and it was, I believe, April of 2024, it was the
17 Decertification Opinion, and what he identified was this
18 mismatch, as the Court is clearly aware of, between the point
19 of sale damages as calculated by Dr. Conti and the point of
20 payment as certified in the classes.

21 And what Judge Kugler said, because it was raised
22 obviously in the context of ascertainability, and what he said
23 is this is not going to be a problem because plaintiffs will
24 have to put forward a "translating mechanism," some way to get
25 from the point of sale damages that are on the exhibit that

1 counsel reviewed to the way that the classes were certified,
2 and that wasn't done, Your Honor.

3 CHIEF JUDGE BUMB: Okay. So the witness has said she
4 didn't do that. So what's the defendants' argument? The whole
5 thing goes out?

6 MS. BROWN: Well, it's, yes, a 702 argument, Your
7 Honor. Now we don't have a fit. Now we have state-specific
8 damages that do not match the state-specific classes.

9 CHIEF JUDGE BUMB: Or we have: Goes to the weight
10 because the assumptions were made that they were one and the
11 same. And so it just seems to me somewhat unrealistic to have
12 this witness then go and look at, I don't know how many, you
13 know, millions of prescriptions and determine who was the
14 physician and where was it filled. That seems to be -- you
15 know, I used the word "nitpicky," but it does seem to be -- I
16 don't think that that's what 702 requires.

17 Isn't she not permitted in the course of her
18 experience, this is what they do in the health industry; that
19 there can be some crossing of borders as she said? But she can
20 make that assumption.

21 MS. BROWN: Well, I think the fit though, the lack of
22 connection between how the damages were calculated here --

23 CHIEF JUDGE BUMB: Right.

24 MS. BROWN: -- and how the classes were certified is
25 a 702 issue, Your Honor. Because what the jury -- this will

1 not assist the jury who is going to be asked to say in the
2 state of Alabama, did Defendant Teva pay for, you know, or did
3 plaintiff pay for a certain amount of valsartan. That's not
4 what these calculations tell us. And so it is an excludable
5 opinion, Your Honor, because it doesn't fit the theory that
6 they --

7 CHIEF JUDGE BUMB: Okay. You don't throw it out
8 entirely. She's already testified that she's made that
9 assumption, and the jury can look at the figure for Alabama and
10 say, well, it's 16,441, so, you know, there might be, I don't
11 know, 5 percent, so let's make it, I don't know, 12. I don't
12 know.

13 MS. BROWN: Well, but, Your Honor, I don't believe
14 it's a situation where we don't know if it's the prescriber, we
15 don't know if it's the patient. Maybe at the margins, as the
16 Court is suggesting, you take a little discount. It's
17 something different entirely.

18 It's where -- the classes were certified based on did
19 the TPP pay in the state of Alabama, Georgia, you know, fill in
20 the blanks. And so it's not something as the Court is
21 proposing. And it does seem reasonable perhaps in another
22 context, but it's not a situation where you could say, sure, it
23 goes to weight. I'll discount 5 or 10 percent because maybe
24 somebody lived in Philly and came to Camden to fill a
25 prescription. It's actually a complete mismatch, as Judge

1 Kugler said.

2 CHIEF JUDGE BUMB: What's the mismatch?

3 MS. BROWN: The mismatch is Dr. Conti has calculated
4 damages at the point of sale. So that's the pharmacy, right?

5 CHIEF JUDGE BUMB: Okay.

6 MS. BROWN: Where somebody goes in, CVS, fills a
7 prescription, that's the prices Dr. Conti has used. We can
8 talk about whether that's pharmacy or prescriber, as the Court,
9 I think, rightly identifies. It's probably a marginal
10 difference. The problem here is the classes were certified
11 based on where the TPP -- if the TPP paid in that state.

12 And so, Your Honor, that has nothing to do with where
13 a prescription was filled. These TPPs pay in almost all
14 instances through PBMs that could be located in completely
15 different states.

16 And this really does tie, Your Honor, and I know the
17 Court's already ruled on this, but is why the IQVIA data is
18 unreliable. What would have been more reliable and what
19 Dr. Conti had access to for the two Named Plaintiffs is the
20 actual claims data from the TPPs. That would tell you actually
21 where these payments were happening, what was actually paid.

22 The data she's relying on is aggregated data at the
23 pharmacy at best. Maybe prescriber at worst. But what we know
24 it's not is a calculation of where the TPP -- whether or not
25 the TPP paid.

1 CHIEF JUDGE BUMB: Why didn't you just use the actual
2 claims data that she's referring to? Can you answer that
3 question?

4 THE WITNESS: I don't -- it's not comprehensive. I
5 don't have it all. Whereas IQVIA has the entire U.S. national
6 sales of all prescription drugs in the United States.

7 CHIEF JUDGE BUMB: What would make it comprehensive?

8 THE WITNESS: So, for example, there is no public
9 dataset for all of Medicare claims at this point in time that I
10 can look at. I would have to get that data. I don't have that
11 data now, nor does Mr. Gibson.

12 CHIEF JUDGE BUMB: How do you get the data?

13 MR. HONIK: Your Honor, if I may, this is a legal
14 argument now. And there's a fundamental mistake I think that
15 Ms. Brown made.

16 Judge Kugler -- so Ms. Brown started by saying I want
17 to ask questions about "fit."

18 CHIEF JUDGE BUMB: Uh-huh.

19 MR. HONIK: And indeed in the decertification motion,
20 because the Supreme Court ruled in *Comcast* that the damage
21 model has to fit the claims. That's what *Comcast* is about.
22 And they served an extensive brief on this issue.

23 And Judge Kugler wrote the following: "The *Comcast*
24 situation is exactly what the parties do not have here." He
25 determined that there is fit. Because the benefit of the

1 bargain is at the point of sale. Separately, in summary
2 judgment, he reinforced that idea, in summary judgment. They
3 challenged statute of limitations, and the Court again said,
4 "The harm occurs at the point of sale."

5 CHIEF JUDGE BUMB: But the point of sale is the
6 claims data, the actual claims data. Isn't that the point of
7 sale?

8 MR. HONIK: Exactly.

9 CHIEF JUDGE BUMB: But she didn't look at that.

10 MR. HONIK: No. No. She looked at, at the point
11 where the pharmacy dispenses it, and that's what these damages
12 are. And what the Court said after determining the fit is
13 established as a matter of law is the Court was concerned that
14 there might be double-dipping or under-awarding on the
15 administration of the award itself and said there may need to
16 be a translating mechanism to cross-reference. And the Court
17 cited to an antitrust decision called *RealPage*. And that was a
18 Fair Credit Reporting Act case where a class of would-be
19 persons were injured reputationally by an improper credit
20 reporting, and the data was anonymized except it was located
21 elsewhere.

22 And so what the Court was pointing to is that in
23 administering the damages in this case, not a matter for the
24 jury, but when this case gets administered, when the damages
25 need to be allocated fairly so as not to have, for example,

1 double-dipping, you have a prescription filled in New Jersey
2 and the payor is in Pennsylvania, we don't want them taking
3 from two buckets.

4 And so all the Court was saying is do what they did
5 in *RealPage*, and look at the available data to cross-check.
6 That's it. Fit has been established as a matter of law under
7 *Comcast*.

8 CHIEF JUDGE BUMB: I don't know how fit can be
9 established because the *Daubert* hearing is occurring today.
10 And so to say that Judge Kugler, who did not hold a *Daubert*
11 hearing which this Court is holding, must find the element of
12 fit. So to stand before me and say that fit has been
13 established, that's why we're here. So either I'm missing
14 something or somebody -- I --

15 MR. HONIK: So I misspoke. It may not be
16 established. But the Court wrote in its Decertification
17 Opinion, in response to the very argument that Ms. Brown is
18 espousing now, that the *Comcast* situation, which is the fit
19 requirement, is exactly what the parties do not have here.

20 And so there's a conflation, that's all I'm trying to
21 suggest, Your Honor, between 702 and the *Comcast* requirement of
22 fit. There is fit enough to go to a jury. What there may not
23 be yet is a translating mechanism, to the extent one is needed,
24 and we don't think it is required, to cross-check to make sure
25 the allocation of entitlement of an award is properly

1 allocated.

2 But that has nothing to do with Dr. -- Professor
3 Conti's ability to say harm occurs at the point of sale. I
4 took the value of these prescription drugs when they were sold
5 at the pharmacy counter by looking at gold standard data,
6 period, the end.

7 MS. BROWN: May I approach with the actual Order and
8 just direct Your Honor to the language I'm referring to?

9 CHIEF JUDGE BUMB: Okay.

10 MS. BROWN: And, Your Honor, for the record --

11 CHIEF JUDGE BUMB: I'm starting to believe that we
12 need to start all over.

13 MS. BROWN: Your Honor, I just turned to page 6.
14 That's the paragraph.

15 CHIEF JUDGE BUMB: And maybe we will.

16 MS. BROWN: And, Your Honor, may I proceed?

17 CHIEF JUDGE BUMB: No.

18 MS. BROWN: Okay.

19 (Pause.)

20 CHIEF JUDGE BUMB: I don't know that this says what,
21 Mr. Honik, you say it says.

22 What's the point you're trying to make?

23 MS. BROWN: Your Honor, I think the point is that the
24 translating mechanism that would make these damages fit the
25 facts of the case and make them useful to the jury, reliable

1 and helpful and relevant, has not been accomplished here.

2 These are damages that were calculated, as Judge
3 Kugler points out, based on the point of sale. That is
4 mismatched, to use the Court's term, with the way the classes
5 were certified, which is point of payment.

6 Dr. Conti, since the date of this decision, did not
7 disclose, nor, frankly, Your Honor, do I believe it's even
8 possible based on the data she used, a translating mechanism
9 that the Court said would be required to bridge this mismatch
10 such that her damages would fit the way the classes were
11 certified.

12 CHIEF JUDGE BUMB: The class was certified by point
13 of payment?

14 MS. BROWN: Correct, Your Honor. And that's, if you
15 look at page 6, what Judge Kugler says what is needed is what
16 the Third Circuit allows -- a translating mechanism that aligns
17 the missed match point of sale jurisdictions to the point of
18 payment locations.

19 CHIEF JUDGE BUMB: So if the class was certified by
20 point of payment, this witness has testified about the point of
21 sale. What am I to do with that?

22 MR. HONIK: Your Honor --

23 CHIEF JUDGE BUMB: Yeah.

24 MR. HONIK: -- the class was certified on the basis
25 of point of sale, period, not the point of payment.

1 CHIEF JUDGE BUMB: Okay. Can someone help me resolve
2 that issue?

3 You folks have such a divergent view of what this
4 case is all about. It's quite remarkable.

5 Can I see what the class certified was?

6 MS. BROWN: Yes, Your Honor.

7 CHIEF JUDGE BUMB: And I'm still waiting to see what
8 the causes of action are in this case.

9 I've never seen such a disconnect for a case as old
10 as it is.

11 MS. BROWN: And, Your Honor, if I could approach,
12 what I have available here for the Court was what was on
13 Dr. Conti's reliance list, which was as of 2021, the proposed
14 classes, and it has that point of payment.

15 CHIEF JUDGE BUMB: Well, where is Judge Kugler's
16 Order certifying the class?

17 MS. BROWN: I'll have to get that for Your Honor. I
18 don't have it in my materials.

19 CHIEF JUDGE BUMB: Mr. Honik, do you have it?

20 Because if the class was certified as to the point of
21 payment and this witness is testifying about the point of sale,
22 their argument is very well taken.

23 MS. BROWN: And, Your Honor, it was. And we need to
24 just have the ability to print it out. These were the
25 proposals that were then adopted. And the relevant language

1 is, it's these subclasses.

2 CHIEF JUDGE BUMB: May I see it?

3 Are you representing that this was what was signed by
4 Judge Kugler?

5 MS. BROWN: Yes, Your Honor. This was, I think,
6 proposed by the plaintiffs in 2021. And it's just this "paid
7 any money in the particular state" language that when the
8 ultimate classes were certified, the language remained.

9 CHIEF JUDGE BUMB: What do you want me to look at?

10 MS. BROWN: So, Your Honor, if you -- where I
11 underlined for each -- for our purposes of this discussion.

12 CHIEF JUDGE BUMB: I see it.

13 MS. BROWN: Okay.

14 CHIEF JUDGE BUMB: It says, "Paid any amount of money
15 in: Alaska."

16 MS. BROWN: Yes, Your Honor.

17 CHIEF JUDGE BUMB: Arizona, California. That to me
18 says point of payment.

19 MR. DAVIS: Your Honor, may I address?

20 CHIEF JUDGE BUMB: If you folks are not even agreeing
21 on what was certified, I think I may have to take another
22 break.

23 Go ahead.

24 MR. DAVIS: So I think Dr. Conti, Professor Conti
25 testified that the TPPs at the point of sale, at the pharmacy

1 counter there's an adjudication that occurs. The consumer pays
2 with a credit card usually. The amount that the TPP is obliged
3 to pay legally is set and determined at the point of sale.
4 There is -- this is case law that goes back to the foundations
5 of the --

6 CHIEF JUDGE BUMB: You might be right. But that's
7 not how Judge Kugler certified the class. What am I to do with
8 that?

9 MR. DAVIS: Well, the consideration, the promise to
10 pay is the same thing as a payment. Our legal system has
11 always recognized that. And so the TPPs have made a promise to
12 pay at that pharmacy counter when that live adjudication
13 happens. And that's the consideration, that's where they're
14 bound to pay, and that's where they're effectively deemed to
15 pay.

16 And I think Judge Kugler in his Summary Judgment
17 Opinion, if you look at page 40 of it, he wrote -- and this is
18 with respect to the defendants' statute of limitations
19 argument -- he wrote that for TPP's economic loss claims for
20 breach of express warranty, tender of delivery occurs when the
21 TPP paid for or reimbursed their consumers' VCDs. This date
22 occurs when the consumer paid the pharmacy or dispensary for
23 the VCD script because at that time the dispenser will also
24 charge the TPP for its portion of the reimbursement, thus the
25 date of VCD script purchase serves as the trigger date for the

1 express warranty statute of limitations.

2 I think that's a recognition that at the point of
3 sale, that obligation to pay, which is the same thing as a
4 payment legally, and under our -- and I can cite to you
5 18th Century Supreme Court case law on this, the promise to pay
6 is the same thing under our legal system.

7 And so the place of payment is the point of sale
8 here, even if like some wire banking transfer --

9 CHIEF JUDGE BUMB: You're saying they're one and the
10 same?

11 MR. DAVIS: Yes. If -- and it's all -- I mean, think
12 about it like a credit card.

13 CHIEF JUDGE BUMB: But your witness just said
14 something contrary. They can be different she said.

15 MR. DAVIS: Think about a credit card transaction,
16 like the consumer goes and pays with a credit card, they later
17 settle their bill a month later. It's a similar situation. I
18 don't think anyone would say that the consumer who like, you
19 know, in Ms. Brown's example traveled here from Philadelphia
20 and then went home to Pennsylvania to pay their credit card
21 bill, I don't think anyone would say that their cause of action
22 arises in Pennsylvania. It's the same -- the same situation
23 here.

24 The TPP is incurring the financial obligation to pay
25 at the pharmacy counter, and that's deemed to be where they

1 paid.

2 CHIEF JUDGE BUMB: You're saying they're one and the
3 same?

4 MR. DAVIS: Yeah. Yes, Your Honor. Yes.

5 CHIEF JUDGE BUMB: Well, what do you do about a
6 witness who just said the contrary; that they are not
7 necessarily the same? Unless we're talking about something
8 different.

9 MR. DAVIS: Well, I think she might have been
10 referring to something different.

11 THE WITNESS: I think we were talking about something
12 different.

13 MR. DAVIS: Yeah. I think she might have been
14 referring to the situation where a consumer travels across
15 state lines and that the pharmacy -- the place of that the
16 doctor is writing the script might not be the same thing as the
17 same place as where the consumer -- I'll let you speak to that,
18 if I've got it wrong.

19 THE WITNESS: No, that's exactly -- that's exactly
20 right.

21 So if I see a doctor in Philadelphia, he writes me a
22 script and then I fill that prescription in New Jersey, that
23 filling of that prescription is recorded in New Jersey, or it
24 might -- so, but -- and the payment occurs in New Jersey at the
25 pharmacy counter.

1 CHIEF JUDGE BUMB: And what did you use, point of
2 payment?

3 THE WITNESS: I used point of payment -- no. I used
4 point of sale which generally is exactly the same thing as
5 point of payment. Why? Because when the pharmacy counter --
6 when the patient is getting the prescription, the pharmacy
7 actually runs the patient's insurance. It tells the patient
8 exactly how much they have to pay at the pharmacy counter, and
9 it also sends a claim to the insurer for how much that payment
10 has to be made. It's at that point in time that the payor, the
11 TPP in this case, is obliged to pay. So that all gets
12 generated at the pharmacy counter at the time or at the place
13 where the purchase -- where the patient picked up their
14 prescription.

15 CHIEF JUDGE BUMB: And you looked at the point of
16 sale?

17 THE WITNESS: I looked at the point of sale, correct.

18 CHIEF JUDGE BUMB: Okay.

19 MS. BROWN: And, Your Honor, two points on that, if I
20 could.

21 CHIEF JUDGE BUMB: Yeah. But, Mr. Honik, you kept
22 saying "point of payment."

23 MR. HONIK: Your Honor, they're one and the same. I
24 think you got it right. The class as certified refers to
25 payment, and the point we're trying to drive maybe inartfully,

1 and I apologize, is that that occurs at the point of the sale.
2 That coincides with payment.

3 CHIEF JUDGE BUMB: Okay.

4 MR. HONIK: They're not different.

5 What the Judge, I think, acknowledged, because he
6 said there's fit. *Comcast* -- he said *Comcast* doesn't apply
7 here. What he did acknowledge is that we don't want to see, in
8 terms of allocation of an award, any mismatch there or
9 double-dipping. That's really what the Court was interested
10 in. And that's strictly an administrative function on the back
11 end.

12 It's not for this jury to determine whether it should
13 come from this bucket or that bucket. That's what *RealPage* was
14 about. And that's all I meant to convey is that it's -- I
15 think it's settled in terms of *Comcast* that there is
16 constitutional fit, and there's no -- there is nothing that
17 undermines the Rule 23 finding.

18 And our position is that POP and POS are the same in
19 this case, and that's what IQVIA gives us.

20 CHIEF JUDGE BUMB: Okay.

21 MS. BROWN: And, Your Honor, I would respectfully
22 disagree and point the Court to the February 26, '24
23 Decertification Order that the Court has at page 6, because
24 Judge Kugler made a finding that they are different. That is
25 the law of this case. His finding is that there is a mismatch

1 between damages based on IQVIA at the point of sale and the TPP
2 point of payment.

3 The choice of law decision, Your Honor, was that the
4 TPP's home state's law would apply. The classes were
5 certified, and I now, Your Honor, have the case management --

6 CHIEF JUDGE BUMB: Okay. So go ahead and -- go ahead
7 and conduct your cross-examination on IQVIA.

8 MS. BROWN: Yes, Your Honor.

9 And as it relates to Dr. Conti, I am pretty much
10 done. I'll just wrap up with two questions.

11 CHIEF JUDGE BUMB: No. I'm going to permit you. I
12 don't know that it goes to the weight of the evidence. You may
13 have a valid point that it's not a -- it's a 702 problem, so
14 I'll hear you.

15 MS. BROWN: Yes, Your Honor. I appreciate it. Thank
16 you very much.

17 CHIEF JUDGE BUMB: Okay.

18 BY MS. BROWN:

19 Q. And, Dr. Conti, you have not disclosed in any of your four
20 reports that counsel went through with you this morning a
21 translating mechanism that would allow you to translate the
22 damages that you calculated at the point of sale to the TPP
23 point of payment as contemplated by Judge Kugler in his Order
24 identifying those two things as different?

25 A. So this issue was just raised with me approximately two

1 weeks ago. And in my view, again, the U.S. pharmaceutical
2 system is completely closed. So it is possible or it is
3 possible to ascertain the location of payment and location of
4 service. In my view, they are generally one and the same, and
5 that's because when patients go to the pharmacy counter, they
6 are -- the claim is being generated. That patient can't walk
7 out of the pharmacy without the pharmacy saying how much the
8 patient has to pay and how much the payor has to pay. So that
9 obligation exists and that happens at the point of sale.

10 CHIEF JUDGE BUMB: But can you answer her question?

11 THE WITNESS: I did.

12 CHIEF JUDGE BUMB: So you didn't do that analysis?

13 THE WITNESS: I was -- this issue was raised to me
14 two weeks ago. And, again, in my view, the point of sale and
15 point of payment are the same. And that's because the
16 obligation to pay for the payor and for the patient occurs at
17 the point of sale.

18 Now, this is an industry that is completely awash in
19 data. So there can be claims, individual claims that could
20 determine the overlap. But I have not been asked to do that at
21 this time, and nor do I have the data to do that at this time.

22 CHIEF JUDGE BUMB: Okay.

23 MS. BROWN: May I follow up on that, Your Honor?

24 CHIEF JUDGE BUMB: Yeah.

25 BY MS. BROWN:

1 Q. When you say you don't have the data to do that, what data
2 are you referring to, Professor?

3 A. So, again, this is a closed system, and so from the time
4 the prescription or the drug leaves the manufacturer's
5 warehouse all the way to the time the pharmacy dispenses the
6 product, there are checks, there are checks that determine
7 where that product goes. And therefore, exactly when it leaves
8 the warehouse and exactly when it is delivered at the pharmacy
9 counter is knowable. I don't have that data, but it is
10 knowable.

11 Similarly, exactly when the patient pays and where
12 the patient pays and exactly when the payor faces the
13 obligation to pay is knowable. That is what is in the IQVIA
14 data. That is what is available in claims data as well.

15 Q. And in terms of the claims data you're referring to, that
16 would come from the TPP itself, correct?

17 A. Well, again, I have aggregated all sales of all products
18 in the United States for the at-issue products. That's what
19 the IQVIA data summarizes for us.

20 Could you in another version look at claims to
21 ascertain how much the -- I mean, it's kind of tautological in
22 some way because the time of when the patient is dispensed the
23 product and walks out of the store, we already know what the
24 patient had to pay and what the TPP is obligated to pay.

25 Q. And in terms of -- I thought I heard you earlier,

1 Professor, and maybe you just misspoke, say that in the
2 *Blue Cross Blue Shield* case you used Xponent IQVIA data like
3 the one you were talking about here. Do you recall that
4 testimony this morning?

5 A. I recall it, yes.

6 Q. Yeah. But actually your expert report from the *Blue Cross*
7 *Blue Shield* case discloses that you used claims data from the
8 plaintiffs in that case, right?

9 A. In another part of the case, yes, I did that.

10 Q. Right.

11 A. So I calculated damages using Xponent data, and I also
12 calculated damages using claims. That was done later on.

13 Q. And in terms of claims data in this case, you only had
14 claims data for Emblem and SummaCare, correct?

15 A. I don't know. I don't recall.

16 Q. You don't remember how many TPPs you had claims data for?

17 A. I don't recall off the top of my head, no.

18 Q. All right. You did not do a class-wide economic damages
19 estimate based on TPP claims data, correct?

20 A. Well, I calculated pharmacy claims as one and the same.
21 So the pharmacy is generating -- the point is, is that the
22 pharmacy is generating the claim which is then being
23 transmitted to the TPP. So it's actually, again, the claim is
24 being generated at the point of sale. So I had nine defendant
25 retailer pharmacy data which I calculated damages for.

1 Q. Right.

2 And when you did that, the number you got was
3 approximately 1 billion, with a B, dollars less than the number
4 you got when you calculated using the IQVIA data, correct?

5 A. But, again, that's because the nine retailer pharmacies
6 are a small subsample and a biased subsample of the entirety of
7 the sales of these products into the U.S. market during the
8 class period.

9 Q. And just to answer my question, though, so we can wrap up,
10 when you did that calculation with the pharmacy data you just
11 referred to, the number you got was a billion dollars less than
12 the number you got when you used the IQVIA data?

13 A. Correct. And that's because the prices in the pharmacy
14 claims are biased towards lower priced pharmacies, largely mail
15 order pharmacies. It also doesn't -- it's not comprehensive.
16 There are many pharmacies that paid -- that charge much higher
17 prices for these products that are not in the pharmacy claims.

18 MS. BROWN: Your Honor, I have no further questions
19 for Dr. Conti.

20 I think it's a legal issue that if the Court would
21 allow us to further discuss, I'd be happy to.

22 CHIEF JUDGE BUMB: Well, I want to hear argument on
23 it.

24 Any other questions?

25 MR. HONIK: Briefly, Your Honor, if I may.

1 CHIEF JUDGE BUMB: Okay.

2 REDIRECT EXAMINATION

3 BY MR. HONIK:

4 Q. Professor Conti, you heard or I think it was part of a
5 question the definition of the class as certified. Do you
6 remember that discussion earlier?

7 A. Yes.

8 Q. And I'm looking at the language here which says, "Paid any
9 amount of money. Paid any amount of money."

10 From an economic standpoint, do you have an opinion
11 that you can express with reasonable economic certainty what in
12 economic terms in this supply chain of generic drugs, where and
13 when does payment of any money occur?

14 A. At the pharmacy counter, at the point of sale.

15 Q. And is that for the various reasons that you've described
16 where the consumer parts with his or her money or puts a credit
17 card down and where the affirmative nondelegable, nonnegotiable
18 obligation to pay arises on behalf of the insurers?

19 A. Correct.

20 Q. Is a patient permitted to walk away with their valsartan
21 given to them by the pharmacist without assurance that payment
22 and the obligation to pay is complete?

23 A. Correct. What the issues are in this case are
24 prescriptions that were insured by an insurer. A patient comes
25 into a pharmacy to get a drug, they are going to show their

1 insurance card. It's the insurance card that generates the
2 claim that the pharmacy creates. That claim is going to detail
3 what the patient has to pay and what the payor has to pay.
4 That is the source or that is the location of the obligation.

5 Q. This Court wrote in its Summary Judgment Opinion the
6 following, and I want to ask you from an economic standpoint if
7 you agree with this.

8 "For TPP's economic loss claims of breach of express
9 warranty, tender of delivery occurs when the TPP paid for or
10 reimbursed their consumers' VCDs."

11 Agree or disagree?

12 A. I agree.

13 Q. Do you agree that that date occurs when the consumer paid
14 the pharmacy or dispensary for the VCD script because at that
15 time the dispenser will also charge the TPP for its portion of
16 the reimbursement?

17 Do you agree or disagree?

18 A. I agree.

19 Q. Do you agree with the statement that the date of VCD
20 script purchase serves as the trigger date for express warranty
21 statute of limitations, that is, when the harm arises and the
22 clock runs on the claim? Do you agree with that?

23 A. I do.

24 Q. And is that in every instance because the point of sale
25 coincides economically with the point of payment?

1 A. Correct. The point of sale is when the obligation is
2 made.

3 Q. And did you rely on data that revealed to you from an
4 economist standpoint the values at both the point of sale and
5 the point of payment applying the definitions you just gave us?

6 A. Yes.

7 MR. HONIK: Thank you, Your Honor.

8 CHIEF JUDGE BUMB: Okay. You can step down. Thank
9 you.

10 THE WITNESS: Thank you.

11 CHIEF JUDGE BUMB: All right. Let me hear argument.

12 (Witness left the stand.)

13 MS. BROWN: May I proceed, Your Honor, or should I
14 wait a second?

15 CHIEF JUDGE BUMB: Yes. Go ahead.

16 MS. BROWN: Your Honor, I'll be brief. We spoke
17 earlier today, of course, about Rule 702 and how the advisory
18 committee has now reinforced what this Court and other courts
19 have always already known, which is that you, Your Honor, are
20 the gatekeeper, and it is the Court's responsibility to
21 determine the sufficiency of an expert's basis and application
22 of an expert's methodology. And the advisory committee made
23 clear, as this Court knows, those are not questions of weight.
24 Those are questions of admissibility.

25 And in fact, the advisory committee noted that the

1 reason they were highlighting and underlining and making clear
2 of this gate-keeping responsibility is because issues like that
3 were going to the jury under a misinterpretation of 702 that
4 these were issues of weight, and the advisory committee made
5 clear with the amendment to 702 that these are issues of
6 admissibility, as this Court knows.

7 And so, Your Honor, the issues that we briefed and
8 that I want to briefly discuss here today are issues of
9 reliability and issues of fit.

10 I'll start with fit, which is where we left off.
11 Professor Conti's class-wide calculations simply do not fit the
12 way these classes were certified. And we just heard it, Your
13 Honor, from the witness stand. Dr. Conti has calculated these
14 state damages at a point of sale. And she explained in her own
15 testimony, that's where the consumer makes a payment and the
16 TPP gets a charge or gets an obligation. That's critical, Your
17 Honor, because the classes were not certified by the state in
18 which a TPP became obligated to pay a claim or the state in
19 which a TPP was charged to ultimately pay a claim. That's not
20 how these classes were certified.

21 The classes were certified by the state in which a
22 TPP paid any amount of money. And that is simply not the basis
23 of these state-specific damages by this witness's own testimony
24 and, frankly, by the data that is available from IQVIA.

25 The Court in the 2024 decertification memorandum

1 makes clear that this is a problem for which plaintiffs had to
2 disclose a solution so that this damages model could survive
3 702 and *Daubert*. And they simply didn't, Your Honor. The
4 Court said there's a mismatch. We have point of sale damages
5 calculations and we have classes that are certified based on
6 point of payment, and the Court said it's okay, because what
7 plaintiffs could do is come back to us and give us -- he called
8 it a computer subroutine, a formula, something to translate
9 damages from where she's calculated them to where the classes
10 were certified.

11 CHIEF JUDGE BUMB: Well, how do I get around her
12 testimony that they're one and of the same, except for maybe in
13 a few instances?

14 MS. BROWN: Well, Your Honor, the Court found they're
15 not. I mean, the Court has simply found these are two
16 different -- this is the law.

17 CHIEF JUDGE BUMB: Well, let's assume I agree with
18 you. But that was before the Court had the benefit of the
19 testimony.

20 When you say point of sale and you say point of
21 payment in a vacuum, they sound different.

22 MS. BROWN: Sure.

23 CHIEF JUDGE BUMB: But I now have a witness who will
24 opine that for the most part, and I don't know what that is,
25 but for the most part they are one and the same. A jury is

1 entitled to weigh that.

2 MS. BROWN: Well, two issues, if I could respond,
3 Your Honor. One, I think what Professor Conti is talking about
4 is the point of the prescription, the state of the prescription
5 and the state of the fill is often one and the same. And
6 that's why she said she was actually talking about a different
7 issue.

8 CHIEF JUDGE BUMB: But that's the point of sale.

9 MS. BROWN: That is the point of sale. But that's
10 entirely different from where a TPP pays.

11 So the testimony and the facts and the truth are that
12 almost all of these TPPs pay money through a PBM, a pharmacy
13 benefit manager.

14 CHIEF JUDGE BUMB: Do you have evidence that you're
15 going to introduce to dispute that?

16 MS. BROWN: Oh, 100 percent, Your Honor. That --
17 you'll hear from Mr. Gibson who will explain to you how these
18 payments actually get made here.

19 CHIEF JUDGE BUMB: Who will dispute that the point of
20 sale and the point of payment are different?

21 MS. BROWN: Yes, 100 percent, Your Honor.

22 CHIEF JUDGE BUMB: Okay.

23 MS. BROWN: And I would suggest why it's not an issue
24 of weight is because the Judge knew that. This opinion --

25 CHIEF JUDGE BUMB: No. I think that you're giving

1 Judge Kugler -- I think you're being somewhat unfair to Judge
2 Kugler in the following sense: He didn't have the benefit of
3 the testimony that I am hearing now. As I said, just generally
4 speaking, when someone says "point of sale" and someone says
5 "point of payment," they sound entirely different. But when
6 you have an expert testify that they usually are one and the
7 same, then perhaps had Judge Kugler had the benefit of that
8 testimony, he would not have ruled the way he had. I mean,
9 this was in the context of what? Certification?

10 MS. BROWN: Yes, Your Honor.

11 CHIEF JUDGE BUMB: Well, okay. But we're past that
12 now.

13 MS. BROWN: Well, I would submit two things, Your
14 Honor. First of all --

15 CHIEF JUDGE BUMB: And you're not prejudiced because
16 you're going to introduce a witness that says, yeah, they're
17 not one and the same, and the damages calculations are
18 incorrect.

19 MS. BROWN: But here's why I think it's a 702 issue,
20 Your Honor, is she's not disclosed on that, right? She's
21 disclosed on these state-specific damages that unquestionably
22 she admits to this Court and in her report are coming from the
23 pharmacy counter, right? This is the place where these are
24 created.

25 CHIEF JUDGE BUMB: Yeah.

1 MS. BROWN: And unquestionably, that's not how the
2 TPPs pay, and that's not how the TPPs were certified. So
3 whether she's now going to say, well, I think it's the same or
4 not, that's a gatekeeping issue. Based on what? Based on what
5 analysis that was disclosed to this Court? Nothing. Based on
6 what scientific support, based on what data in IQVIA? That's
7 the reliability issue. And that's the fit issue, is that if
8 she now having learned about this issue two weeks ago now says,
9 oh, it's not a problem because, you know, I in my head think
10 it's the same, she has to have disclosed that opinion and she
11 has to be able to support it.

12 What she disclosed was a point of sale opinion for
13 which there was no translating mechanism that was disclosed, no
14 scientific evidence to support it.

15 CHIEF JUDGE BUMB: But she's saying today that in the
16 industry point of sale is usually or whatever word she used the
17 point of payment.

18 MS. BROWN: But --

19 CHIEF JUDGE BUMB: And that's where the TPPs, you
20 know, you can look at the point of sale, you can look at the
21 point of payment. They're one and the same. Are there
22 instances where they're not? Sure. But for the most part, in
23 the industry, this is what I rely upon and this is how it's
24 calculated.

25 MS. BROWN: Well, Your Honor, again, I think that was

1 her testimony as to prescriber and pharmacy.

2 CHIEF JUDGE BUMB: Yes.

3 MS. BROWN: Which is wholly different from where the
4 TPP pays, right? The mismatch is point of sale --

5 CHIEF JUDGE BUMB: What was her testimony about where
6 the TPP pays?

7 MS. BROWN: There is data that would allow you to
8 know that and I only learned about this issue two weeks ago and
9 mine is point of sale. That's her testimony, Your Honor.

10 CHIEF JUDGE BUMB: Was that her testimony?

11 MS. BROWN: Yes, Your Honor. I mean, where she said
12 it's one and the same --

13 CHIEF JUDGE BUMB: Is she still here?

14 Could you come back up and let me ask that question.
15 I didn't understand that that way.

16 (Witness resumed the stand.)

17 CHIEF JUDGE BUMB: Could you tell me what your
18 testimony is as to in your expert opinion where it is that the
19 TPP is paid?

20 THE WITNESS: The obligation to pay for both patient
21 and the payor is at the point of sale. They are one and the
22 same.

23 CHIEF JUDGE BUMB: I thought that's what she said.

24 MS. BROWN: But, Your Honor, she just said the
25 obligation. We're not -- the class is not the obligation. The

1 class is payment.

2 CHIEF JUDGE BUMB: Do you see a distinction between
3 the obligation to pay and where it was paid?

4 THE WITNESS: I do not.

5 MS. BROWN: May I follow up on that, Your Honor?

6 CHIEF JUDGE BUMB: Sure.

7 FURTHER EXAMINATION

8 BY MS. BROWN:

9 Q. In terms of -- you have assumed for purposes of your
10 calculation that where a TPP is charged or is obligated to pay
11 is where a TPP pays, correct?

12 A. Again, patients can't walk out of a pharmacy without
13 payment being assessed. That is what the claims generation is
14 in this market.

15 So a patient is told how much they're going to pay
16 and the plan is told how much they are going to pay. The plan
17 is obligated to pay that amount.

18 Q. I understand the obligation.

19 In terms of the payment, like how and when and by
20 what method money transpires, that's not part of your analysis?

21 A. Of course it is.

22 Q. Your analysis is where the obligation arises, correct?

23 CHIEF JUDGE BUMB: Which is the same -- she said and
24 where the obligation arises is where the claim was paid. I
25 mean, that's what she said. I mean, your expert will dispute

1 that, but that's what she said.

2 MS. BROWN: I understand, Your Honor. But I would
3 suggest to the Court that's not the class. The class is not
4 obligation. It's payment.

5 CHIEF JUDGE BUMB: I know. But they're one and the
6 same, in her testimony. You may not agree with it.

7 MS. BROWN: I understand, Your Honor. I understand.

8 CHIEF JUDGE BUMB: Okay.

9 MS. BROWN: And --

10 CHIEF JUDGE BUMB: Go ahead, anything else for the
11 witness?

12 MS. BROWN: Nothing else for this witness, Your
13 Honor.

14 CHIEF JUDGE BUMB: You can step down.

15 THE WITNESS: Thank you.

16 (Witness left the stand.)

17 MS. BROWN: And, Your Honor, I would continue to
18 suggest, Your Honor, is that there is not a scientific basis
19 for that. She didn't review any claims data aside from two of
20 the TPPs that would permit an evaluation of where and through
21 whom and, importantly, in what state that payment occurs.

22 So on this issue, Your Honor, on this mismatch/fit
23 issue, I do not believe this opinion could possibly survive 702
24 or, frankly, reliability for that point, because the question
25 is going to go to the jury on a state-by-state basis.

1 And if the state-by-state numbers that they are given
2 are not appropriate to a liability question, then that's not
3 helpful. That's not relevant to the jury, and it doesn't fit
4 the theory of liability.

5 And so, Your Honor, respectfully on that score, these
6 state-specific damages do not survive 702 or Daubert. And we
7 have moved in the papers, as Your Honor will see, on this very
8 issue. And I would submit to the Court, and I know the Court's
9 reviewed them, there was no response.

10 On this state mismatch issue, I think there was one
11 sentence in the opposition at the very end. So there has been
12 a striking silence on the other side of the aisle on this issue
13 that I believe is dispositive.

14 Briefly, Your Honor, the other issues we raised in
15 our briefing are issues of reliability, particularly as it
16 relates to the IQVIA data, and I know the Court has ruled so
17 I'll just make a record very quickly.

18 Dr. Conti did two different calculations. One based
19 on the IQVIA data, and she arrived at a damage number of
20 approximately 1.3 billion. And then she did one based on the
21 available pharmacy data which is actual transaction data, and
22 she arrived at a number of approximately 300 million. There's
23 a billion dollar disconnect, Your Honor.

24 IQVIA itself, and we cited it in our papers, cautions
25 people who buy their data not to rely on it in a legal

1 proceeding to establish any fact or any evidence.

2 IQVIA in correspondence says one of the reasons we do
3 that is because our data is based on surveys and estimates, and
4 pharmacies often when they're answering the survey, they tell
5 us the list price, you know, the rack rate as opposed to the
6 amounts they actually collect. And so IQVIA themselves says we
7 tell everyone who uses our data to use that data with caution.
8 There's a whole list, and we cited it, Your Honor, in the
9 briefing of statements by IQVIA itself that this data is not
10 reliable for the purposes which she used it.

11 And so, Your Honor, for that reason I don't believe
12 it's an issue of weight. We -- the Court as gatekeeper is
13 deciding -- has to decide before this gets to a jury that this
14 was reliably applied, and the source of this data says don't
15 use it for this purpose.

16 You'll hear, Your Honor, from Mr. Gibson who actually
17 took the claims data from the two TPPs for which we have
18 information and compared it to IQVIA to see, like, let's
19 double-check this. Can we repeat this? Can this, you know, is
20 this reliable? And you'll hear that it unsurprisingly resulted
21 in numbers from IQVIA that were 60 or 70 percent higher than
22 the actual number from the TPP plaintiffs.

23 CHIEF JUDGE BUMB: Why didn't you cross her on that?

24 MS. BROWN: Well, I -- I should have, I guess, Your
25 Honor. I understood the Court to have already ruled on that

1 this was --

2 CHIEF JUDGE BUMB: No. I said I was changing my mind
3 and you could go forward.

4 MS. BROWN: I apologize, Your Honor.

5 Then you'll hear from Mr. Gibson on this, Your Honor.

6 CHIEF JUDGE BUMB: When?

7 MS. BROWN: I think he's scheduled to testify next --

8 MR. OSTFELD: Next Tuesday, Your Honor.

9 MS. BROWN: And that's a check, right, Your Honor? I
10 mean, that's a way you could check, hey, I got the claims data
11 from the pharmacy and it's a billion dollars less, what could I
12 possibly -- you know, let me check this out. There's a way
13 that could have been done. Dr. Conti didn't do that, and I
14 think it further establishes that when IQVIA says don't use
15 this data for direct evidence in a legal proceeding, we know
16 why. Because when we look at the actual data, we see that it
17 is unsurprisingly overinflated.

18 And, Your Honor, we heard extensive testimony earlier
19 in the day on Dr. Conti's worthlessness opinion, and I'm going
20 to leave that record where it is, and --

21 CHIEF JUDGE BUMB: Well, I have a question on that.
22 But let me ask your adversary the question.

23 MS. BROWN: Okay. Thank you, Your Honor.

24 CHIEF JUDGE BUMB: On what basis does she rely -- I
25 really wasn't following the testimony. What is the basis by

1 which she can opine that the drugs were worthless?

2 MR. HONIK: Your Honor --

3 CHIEF JUDGE BUMB: She can assume that they were
4 worthless and do her calculation.

5 MR. HONIK: Respectfully, Your Honor, I --

6 CHIEF JUDGE BUMB: How can she opine that they were
7 worthless? That's a jury question.

8 MR. HONIK: I agree it's a jury question.

9 CHIEF JUDGE BUMB: Okay.

10 MR. HONIK: And I believe that the jury has to
11 evaluate the foundation for Professor Conti's opinion that they
12 were worthless. And she didn't assume it in the least, Your
13 Honor. She built it on a foundation based on two things:
14 Economic principle, her years of experience, and FDA
15 regulations.

16 The syllogism goes like this. And it was recognized
17 by Judge Kugler in his Class Cert Opinion in which is he
18 endorsed her methodology of getting to zero. The syllogism
19 goes like this. No one disputes that a drug which is
20 adulterated cannot be sold lawfully in the United States.

21 The economic implication of being unable to sell a
22 drug in the marketplace from an economist standpoint is that it
23 cannot be assigned a nonzero value, has zero value, merely
24 because it can't be sold because it's adulterated. And it's
25 adulterated and proscribed from being sold by law in the United

1 States.

2 Any economist will tell you that if something is
3 illegal to sell, it is ascribed a zero value. That's how
4 Professor Conti got to zero, as --

5 CHIEF JUDGE BUMB: But she cannot opine -- she cannot
6 opine that these drugs were worthless from day one. That is a
7 jury question. If there were a recall on day one and they were
8 prohibited from being sold, she can. But from day one, she
9 cannot make that opinion, because that is a jury question.

10 MR. HONIK: I --

11 CHIEF JUDGE BUMB: And because it crosses over into
12 your warranty claims. Your warranty claims are, they had no
13 value. The defendants' response is they had some value. So
14 how can an economist who's looking strictly at damages where
15 there's been no recall and no finding of adulteration, because
16 that's what the jury's got to do, how can Professor Conti make
17 that opinion? That's for a jury to decide.

18 MR. HONIK: I -- I agree with the latter statement.
19 The jury has to -- in order for all of our damages to be
20 assessed in our favor --

21 CHIEF JUDGE BUMB: Yes.

22 MR. HONIK: -- a jury would have to conclude that the
23 defendants' drugs were adulterated as of 1/1/2012.

24 CHIEF JUDGE BUMB: Fine.

25 MR. HONIK: And we will demonstrate that. What --

1 CHIEF JUDGE BUMB: But she can't say that.

2 MR. HONIK: I agree.

3 CHIEF JUDGE BUMB: Okay.

4 MR. HONIK: I agree. And so if she assumed and she
5 was asked to assume that they were in fact adulterated, what
6 are the damages that flow from that. That's what she did. She
7 didn't assume zero value. She assumed adulteration, and
8 there's a difference.

9 CHIEF JUDGE BUMB: No. But you're trying to
10 back-door in the jury's job.

11 She can't testify that they were adulterated and
12 therefore they had no value. She can testify that they were
13 adulterated and I assumed for purposes of my analysis that they
14 had no value.

15 A jury can determine that they were adulterated but
16 nonetheless had a value.

17 MR. HONIK: I don't know how the jury can do the
18 latter, Your Honor, because --

19 CHIEF JUDGE BUMB: I don't either.

20 MR. HONIK: Because --

21 CHIEF JUDGE BUMB: This is where I was this morning.
22 I don't know how a jury determines, but then I'm told that
23 there are experts that will testify to it.

24 I do not know how the parties are going to present a
25 case to the jury that on what evidence can a jury find that

1 these adulterated drugs had value. I don't know. Because what
2 I think everyone continues to ignore is that for many years
3 these drugs were sold. For many years they served their
4 therapeutic -- I'm saying just generally speaking. I'm not
5 taking either side. I'm just saying this is the arguments.
6 For many years they had a therapeutic value. There then came a
7 recall. They could not be sold. Clearly they had no value
8 once they could no longer be sold.

9 But up until that point, what value did that drug
10 have? Putting aside whether or not the defendants mislead,
11 fraudulently induced, et cetera, whatever the fraud claim is,
12 putting that all aside. But there has to be some measure by
13 which a jury can say, yes, there was some value to these drugs
14 because it saved lives, et cetera. Then we get into, this is
15 where the big dispute between the parties is, but then aren't
16 we really getting into the issue of causation? Shouldn't we,
17 the defendants, be permitted to say these drugs were totally
18 fine, they don't cause cancer?

19 And this Court has resisted going there because it
20 was satisfied that that issue could be avoided in this upcoming
21 trial, and now I sit before you all and say I'm not so sure
22 about that.

23 MR. HONIK: Your Honor, the defendants who put a
24 carcinogen in the drug for years and years and infected it into
25 the U.S. drug supply cannot go scot-free. Let me start there.

1 There has to --

2 CHIEF JUDGE BUMB: I think we all agree on that.

3 MR. HONIK: And so therefore the law imposes a
4 consequence. And we have asserted the consequence sounds in
5 breach of warranty --

6 CHIEF JUDGE BUMB: Yes.

7 MR. HONIK: -- based on benefit of the bargain.

8 CHIEF JUDGE BUMB: Right.

9 MR. HONIK: It is black letter law that the delta or
10 difference between the value of the drug at the moment you
11 acquired it or paid for it and its actual value are your
12 damages.

13 In that way, coupled with the FDA's absolutely
14 profound interest in protecting our drug supply, it's not a
15 small thing that there was a carcinogen in there. We have
16 charts that show zero sales the minute -- the minute that the
17 adulteration was revealed.

18 CHIEF JUDGE BUMB: Right. Of course.

19 MR. HONIK: And that's the way it should have been
20 from the beginning.

21 CHIEF JUDGE BUMB: Okay.

22 MR. HONIK: And what it falls to us to prove to this
23 jury is that that was known or knowable going all the way back
24 to 2012.

25 Remember, this was a process change. ZHP was making

1 uncontaminated valsartan before this all happened.

2 CHIEF JUDGE BUMB: I am not disagreeing with anything
3 you're saying thus far.

4 If the proofs are that the plaintiffs will stand
5 before the jury and they will prove that the defendants knew
6 from day one or day 30 or whatever day that they were putting
7 carcinogens in, in a drug, okay, that is the element of
8 scienter, that's the element of fraud, and the plaintiffs have
9 every right to pursue those damages, right?

10 But I think where we keep going back and forth is, it
11 seems to me that the plaintiffs are presenting to the Court a
12 cause of action that I -- I can't -- it's this -- it's the
13 plaintiffs' theory, and the cause of action I can't -- I can't
14 put a round peg in a square hole kind of a concept. Because
15 the plaintiffs wanted to present a case that says that because
16 they were adulterated from day one, ipsi dixit, they were
17 worthless. What is that cause of action? It can't be the
18 common law fraud one, because that has a scienter element into
19 it. It can't be the breach of warranty because that has --
20 they are entitled -- they, the defendants, are entitled to say,
21 no, they weren't worthless. They had value. What is that
22 cause of action that says on day one because they were
23 adulterated they had zero value and we're entitled to damages
24 from day one moving forward? What is that cause of action?
25 Because that sounds like it's strict liability to me, and

1 that's the problem I'm having.

2 What is that cause of action?

3 MR. HONIK: Your Honor, the question is this: On
4 January 2, 2012, when a patient hoping to control their blood
5 pressure walked into a New Jersey pharmacy and bought valsartan
6 which we'll show had a carcinogen in it, what is that patient
7 entitled to? And I don't say that rhetorically.

8 The answer is abundantly clear in the law, in
9 every -- in all 50 states. They are entitled to the benefit of
10 their bargain, which is measured between the value that they
11 got and the value that they should have gotten.

12 Now --

13 CHIEF JUDGE BUMB: And so to --

14 MR. HONIK: -- presumably --

15 CHIEF JUDGE BUMB: And so --

16 MR. HONIK: And you have yet to hear this.

17 CHIEF JUDGE BUMB: Well, hang on a second.

18 MR. HONIK: The defendants --

19 CHIEF JUDGE BUMB: And so they, the defendants, are
20 presented with just because the plaintiffs say that there was a
21 carcinogen in it does not mean per se that it had no value.
22 They are entitled to say, yes, it had nitrosamine in it, but it
23 didn't affect the therapeutic value. It didn't cause, and
24 here's that word "cause," it didn't cause injury, et cetera.
25 That's the problem.

1 MR. HONIK: And we say no.

2 CHIEF JUDGE BUMB: I know. On what theory?

3 MR. SLATER: Can I --

4 MR. HONIK: Because under the United States Code, the
5 sale of that drug on January 2, 2012 should not have occurred.

6 CHIEF JUDGE BUMB: Agreed.

7 MR. HONIK: Must not have occurred.

8 CHIEF JUDGE BUMB: What's the cause of action? Don't
9 quote the U.S. code to me, and don't quote the CFRs to me.
10 What's the cause of action?

11 MR. HONIK: Breach of express warranty.

12 CHIEF JUDGE BUMB: Not every CFR, not every U.S. code
13 creates a private cause of action.

14 MR. HONIK: I agree.

15 CHIEF JUDGE BUMB: Okay.

16 MR. HONIK: It's a breach of express warranty, which
17 has been certified. It's also a fraud, and it's also a
18 violation of the Consumer Protection Law, in that -- in that
19 when that patient got the label and it said valsartan, it was
20 by design not permitted to contain a nitrosamine in it, which
21 is a highly genotoxic carcinogen. And that creates a warranty
22 which in terms of the TPPs, this Court, Judge Kugler has
23 determined has been established. That warranty was there. And
24 we say that we're going to demonstrate that it was breached;
25 that there are a set of incredible regulations in this country

1 to protect all of us from these drugs reaching the marketplace.
2 And the consequence of those drugs coming in is that that
3 individual is entitled to his or her money back. That is the
4 bottom line. That is black letter law of warranty law.

5 CHIEF JUDGE BUMB: Fine.

6 MR. HONIK: The bargain wasn't made.

7 CHIEF JUDGE BUMB: Fine. You're going to present
8 your case that it was breached because it had -- for whatever
9 theory it is, it had nitrosamine in it. They're going to
10 present their case that said, no, it did not. You're going to
11 then say here's our damages. We get zero. They're going to
12 say, no, because you got the benefit of the bargain, it was a
13 health -- it was a blood pressure medicine that worked. And
14 that will be for what the jury will decide.

15 MR. HONIK: Well, respectfully, I think --

16 MR. SLATER: Ruben, may I?

17 CHIEF JUDGE BUMB: Mr. Slater, you've been patient.

18 MR. SLATER: For the first time in my life. Thank
19 you.

20 I want to give a little bit of context and hopefully
21 help to deconstruct this. I'm not going to take a long time.

22 Hai Wang is a 30(b)(6) corporate representative for
23 ZHP and the U.S. representatives, the U.S. subsidiaries. He
24 testified that every single person who paid for the drugs did
25 so based on a warranty that the drugs were AB rated and USP

1 compliant. That was the warranty that was provided to anyone
2 who bought them. That's his testimony. That's already been
3 locked down.

4 CHIEF JUDGE BUMB: Right.

5 MR. SLATER: So I wanted to give that to Your Honor
6 just to give you context of what the actual testimony will be.

7 That warranty was not correct.

8 CHIEF JUDGE BUMB: That's right.

9 MR. SLATER: Because the drugs from day one that are
10 at issue in this case were not AB rated and were not USP
11 compliant, because AB rated means therapeutically equivalent,
12 which means has the same quality and purity, and it did not.

13 The warranty claim has no scienter or knowledge
14 element. We obviously talked about that earlier today. And
15 I'm hoping that as we go through this, I know it's a lot, that
16 the cGMP element of it, we thought we should, one, essentially
17 should win on essentially a strict liability basis. Judge
18 Kugler and Your Honor have disagreed and said, no, we're going
19 to let the defense argue, well, it wasn't adulterated.

20 CHIEF JUDGE BUMB: Right.

21 MR. SLATER: At least at this point. And that's
22 fine. We understand the ruling.

23 CHIEF JUDGE BUMB: Right.

24 MR. SLATER: And they're going to argue whatever they
25 can argue, but that's --

1 CHIEF JUDGE BUMB: Right. I think they're saying the
2 same thing. They're representing that it's therapeutically
3 equivalent and that the drug does what it was supposed to do.
4 You're saying, no, it didn't. They're saying, yes, they did.

5 MR. SLATER: Well, they're saying they want --
6 they're -- I guess in general they're taking the position
7 they're not liable. But unfortunately their witnesses under
8 oath who represented the company said we could never have sold
9 it ever with this in it --

10 CHIEF JUDGE BUMB: Okay.

11 MR. SLATER: -- and we never would have. And the day
12 we found out we stopped selling it.

13 CHIEF JUDGE BUMB: Okay.

14 MR. SLATER: So I don't think there's going to be an
15 argument that they actually say, you know, it was fine to sell
16 it all along.

17 CHIEF JUDGE BUMB: No. But I think that the parties
18 keep conflating there is a distinction, a material distinction
19 between saying we could never have sold it versus it was
20 therapeutically effective. And I think that everyone keeps
21 conflating those two -- those two arguments.

22 MR. SLATER: Yes.

23 CHIEF JUDGE BUMB: And you can't.

24 MR. SLATER: Right.

25 CHIEF JUDGE BUMB: It's adulterated. Once it's

1 adulterated, it cannot be sold. No one knew that it was
2 adulterated until well many years later.

3 It does not mean that because it's adulterated it's
4 not therapeutically effective, and that's the defense they want
5 to put on. And that's the defense that they can put on.

6 MR. SLATER: Understood.

7 CHIEF JUDGE BUMB: Getting back to Professor Conti's
8 testimony, I don't find that she's competent to say that just
9 because a drug is adulterated it is worthless. That is for a
10 jury to decide.

11 She's competent to say that once it's rendered
12 adulterated by the FDA, everyone agrees no one should be
13 selling the drug unless the FDA, as it did in this case, gave
14 permission for a little while. But I don't know how she is
15 competent to testify that the drug is worthless once it's
16 adulterated. That is a jury question. So I'm not going to
17 permit that part of the testimony.

18 MR. SLATER: Can I?

19 CHIEF JUDGE BUMB: I'm going to reserve on the IQVIA
20 analysis until I hear from Gibson.

21 MR. SLATER: Your Honor, I'm sorry. I did not want
22 to interrupt you.

23 CHIEF JUDGE BUMB: Yes.

24 MR. SLATER: I was going to get to what you just
25 talked about. If I could just talk to you about it.

1 CHIEF JUDGE BUMB: Okay.

2 MR. SLATER: Dr. Conti, this whole discussion that
3 started with her cross I think has confused a tremendous amount
4 of this argument today, where she was asked about the place
5 where the prescription occurred versus where someone went to
6 the pharmacy, which --

7 CHIEF JUDGE BUMB: I don't think that's relevant.

8 MR. SLATER: It doesn't. It has nothing to do with
9 the case, but I think it confused a lot of the discussion.

10 She's testifying, and I think she really is fully
11 competent and qualified to say under the regulations in this
12 country, if a product is adulterated, there is no legal right
13 to sell it.

14 We asked for a finding as a matter of summary
15 judgment that because the pills were the same from day one till
16 the end, if they were adulterated at the end, they were
17 adulterated on day one. It's just that the FDA didn't know
18 until the end. Saying that her finding can only go forward
19 from the point of the recall is really not helpful because
20 that's when everyone found out and they stopped selling it.

21 But the factual reason why it was adulterated existed
22 on day one. Lack of a competent risk assessment. I'm
23 paraphrasing the entire cGMP findings. But that's really going
24 to be the core thing. They didn't do the right risk
25 assessment, and it didn't comply with the USP.

1 CHIEF JUDGE BUMB: Okay.

2 MR. SLATER: So those are the reasons it's
3 adulterated. So her opinion is not -- she's not going to give
4 the opinion it was adulterated. But she absolutely can say if
5 it was adulterated, and she assumes it was, then it had no
6 value because you're not legally allowed to sell an adulterated
7 drug.

8 CHIEF JUDGE BUMB: No.

9 MR. SLATER: And the defense --

10 CHIEF JUDGE BUMB: Oh, well, she can say that. She
11 can say that you're not legally entitled to sell adulterated
12 drugs. No one's going to dispute that.

13 MR. SLATER: And --

14 CHIEF JUDGE BUMB: But in this case, she can't say
15 that from day one, because we have to focus on the facts of
16 this case, she can't say that from day one these drugs had no
17 value. They can come forward and say that they did have a
18 value.

19 MR. SLATER: Ah. And the way the trial is
20 constructed, they can say -- Your Honor is going to allow them
21 to say there was value. And the flip side is she can say there
22 is no value and the jury decides what the value is. So the
23 expert, Dr. Conti, can say, in my opinion, just like if it was
24 a personal injury case where there's economic numbers going on
25 the board and says this person got hurt and has a million

1 dollars of future medical care needed and puts that on the
2 board and the defense says, well, no, the numbers should be
3 \$50,000, that's all the person needs, and the jury decides
4 what's the final number.

5 Here, Dr. Conti says the value was zero. The defense
6 wants to say there was a value, and we have the issue -- you
7 held an opinion earlier -- and then the jury decides what the
8 value was. But certainly the experts can give opinions on what
9 the value was, and the jury then makes the ultimate finding.
10 This is not usurping the jury. This is giving valid, reliable
11 opinion from Dr. Conti that there was no value. The jury can
12 accept that or not accept it. They can accept or not accept
13 the defense testimony, but there's an absolute right for the
14 economic expert to give that opinion on what the value was,
15 whether it's no value or the value was 2 cents or --

16 CHIEF JUDGE BUMB: But I just think it distorts the
17 record, the facts, the facts that the jury is going to hear.

18 No one in this courtroom will dispute that
19 adulterated drugs declared adulterated by the FDA have no value
20 because you can't sell them. No one can dispute that. But
21 there have been many cases where adulterated drugs unknowingly
22 have been on the market and have had value.

23 So on what basis can Professor Conti say that
24 adulterated, generally speaking, adulterated drugs have no
25 value?

1 MR. SLATER: Well, she's going to speak to -- she can
2 give that general opinion, but in this courtroom she would give
3 the opinion -- she's going to talk about the valsartan drugs
4 under these circumstances, and she can testify certainly to
5 that, these drugs, I'm assuming, were adulterated from day one
6 would meet the definition of adulteration, because that's what
7 we're left to argue, because otherwise we would have won
8 summary judgment. If the finding of adulteration, Your Honor
9 said look --

10 CHIEF JUDGE BUMB: She can testify that on day one if
11 these drugs were adulterated and had the FDA known, et cetera,
12 et cetera, they would be rendered zero, she can say that.

13 MR. SLATER: Okay. And I understand.

14 CHIEF JUDGE BUMB: But there's a lot of ifs in there.
15 But she cannot say that just because they were adulterated
16 means they had no value. Because unless the testimony comes in
17 differently, my understanding of the record thus far is the
18 reason a drug automatically has zero value is the FDA says
19 there's a recall, because I think indisputably there's no
20 sales. Parties can't sell the drug. That's it.

21 But up until that time, and that's when I asked the
22 witness, I said up until that point in time, is there an
23 economic value, and she said yeah. I mean, I was very clear in
24 my question to her, which proves my point; that adulterated
25 drugs have a value up until the point when the FDA says you can

1 no longer sell them legally, or you can no longer sell them.
2 Because legally, because we're conflating two issues. Of
3 course a company can't sell an adulterated drug. But it's not
4 deemed adulterated until -- you know, there's a point in time
5 when let's just -- let's just play devil's advocate for a
6 second.

7 There's been plenty of cases where adulterated drugs
8 have been sold and no one realized that they were adulterated.

9 MR. SLATER: Your Honor, I think the problem with
10 what we're saying here is what Dr. Conti said, she did not --
11 and I thought we got it cleared up, and I think there was just
12 a misspeak. She did not say that until the finding of
13 adulteration, a product that is ultimately deemed to have been
14 adulterated has value.

15 She said a product -- a drug that has risks has
16 value. And she also agreed with Your Honor, reasonably, was do
17 you agree that it had therapeutic value in a clinical sense to
18 the patient, meaning did it help to control the blood pressure.
19 And she said yeah. If it helped, I'm not going to dispute that
20 people's blood pressure was controlled. But she did not
21 concede that that gave it economic value. She drew the
22 distinction between a person getting help physically versus
23 whether it has economic value. And from the perspective of
24 economics, there's no value for the reasons that I'm not going
25 to repeat again because, wow, if it did that again --

1 CHIEF JUDGE BUMB: She can testify that adulterated
2 drugs deemed adulterated by the FDA have no value because you
3 can't sell them.

4 She can testify that she assumes on day one because
5 these drugs were adulterated they had no value and based on
6 that assumption, she did her analysis.

7 MR. SLATER: Thank you, Your Honor.

8 CHIEF JUDGE BUMB: I will reserve on the IQVIA
9 analysis.

10 MR. HONIK: I only wanted to add one additional
11 thing.

12 I was reminded during the lunch break that when we
13 appeared before you on the 23rd of July, that this hypothetical
14 was posed, and you and I discussed it. I looked at the
15 transcript.

16 The recall occurred on July 18th of 2018. And under
17 the rubric that Your Honor just laid out, the valsartan on the
18 18th had no value. It was declared adulterated.

19 CHIEF JUDGE BUMB: Yeah.

20 MR. HONIK: And I posited, well, on the 17th, if the
21 defendants are arguing that it had value then, can they do
22 that? And you said, oh, no, we're not going to have that.

23 And so that's the slippery slope that we're on here,
24 is that you can't -- and just --

25 CHIEF JUDGE BUMB: Well, it had only a little value.

1 I mean, perhaps I didn't appreciate the question.

2 But the FDA said go ahead and, you know, now that the
3 risks are disclosed, you may sell it, but, you know.

4 MR. HONIK: Your Honor, Judge Kugler has written on
5 multiple occasions in the *Daubert* for Expert Williams, in
6 summary judgment, that fact finders make determinations like
7 adulteration and zero value all the time, and that he actually
8 said it was sophistry to say only as of the date of the recall
9 can that occur.

10 CHIEF JUDGE BUMB: Here's what you're going to have
11 to do for me, because I keep going round and round on it,
12 you're going to have to persuade me, and with case law, that a
13 drug that is adulterated, not declared adulterated, but in
14 hindsight found to have been adulterated, is *ipsi dixit* zero
15 value.

16 Because I know of no case that says that a party can
17 go back in time when the -- and I'm just saying what the
18 evidence may show hypothetically. Whether the defendants knew
19 or didn't know is another issue. So I'm going to presume they
20 did not know, and everyone was going about their way. The
21 drugs were doing what they were supposed to do, and then years
22 later there is something found in it that no longer makes it
23 marketable.

24 You'll have to find cases for me that say the fact
25 that for all of those years the drug did what it was supposed

1 to do says it has no value, and then you'll persuade me to
2 reverse course.

3 MR. HONIK: Respectfully, I think the *Blue Cross Blue*
4 *Shield* case is exactly on point --

5 CHIEF JUDGE BUMB: Didn't read it that way.

6 MR. HONIK: -- as is *Debernardis*.

7 Thank you.

8 CHIEF JUDGE BUMB: But then you're going to have to
9 tie it into the cause of actions here. And that's where I keep
10 coming back to, the cause of actions here. Because if they're
11 sounding in strict liability, then -- I don't see common law
12 fraud is strict liability. Certainly express warranty is not a
13 strict liability claim. What is the cause of action? Maybe I
14 have to go back and revisit the pleadings.

15 But you're going to have to tie all of that in to
16 your cause of action, because otherwise it just sounds like
17 it's strict liability. Yep, yep, it was adulterated so they
18 owe us from day one. But what is that cause of action? I
19 don't know. I mean, you might be right. But I am having a
20 hard time tying that in.

21 Am I missing anything from this side?

22 MS. BROWN: No, Your Honor. Thank you.

23 CHIEF JUDGE BUMB: Okay. So I'll reserve in part on
24 Conti. I'll have to hear from other witnesses on that.

25 So can we now go back to some of these issues? I

1 want to give you rulings on some of these issues.

2 There was a -- I mean -- well, let me focus on Conti
3 for a moment, the unjust enrichment claim.

4 MR. DAVIS: Your Honor, that's not a claim that's
5 part of this trial.

6 CHIEF JUDGE BUMB: Okay. There was a motion to
7 exclude on that, and I wasn't clear on that.

8 (Counsel conferring.)

9 CHIEF JUDGE BUMB: The sanctions issue, has that been
10 resolved? You folks have worked that out?

11 Has a check been written?

12 MR. SLATER: I -- we are agreeable. I think they
13 said they need till the 24th to make payment. Obviously that's
14 fine.

15 CHIEF JUDGE BUMB: Okay. So that's taken care of.

16 Let me go through and just give some of my rulings
17 that I don't need argument on.

18 We'll talk about witnesses. I know the plaintiff is
19 concerned that this trial can't be done in the time that the
20 Court's allotted. And if today is any indication, I
21 regrettably agree. But I'll come back to that.

22 Let's see, punitive damages we talked about. I'm
23 looking at -- whose letter am I looking at? Okay. I'm looking
24 at the defendants' letter.

25 Okay. ZHP requests to add new expert.

1 Denied. We're not going to go there.

2 The issue is, is that an expert would testify about
3 the data security laws. I reread Judge Vanaskie's Opinion.
4 They weren't even -- that new law wasn't even in effect at the
5 time that the plaintiffs were attempting to secure this
6 information. And I think the time to present expert testimony
7 on this issue is long gone. So that is denied.

8 Could we -- has the issue on the MSP assignment been
9 resolved? Because I'll resolve it right here and now.

10 MR. SLATER: Judge, I think that we're going to get
11 it done.

12 CHIEF JUDGE BUMB: Okay.

13 MR. SLATER: Myself and Mr. Ostfeld have had some
14 very productive discussions over the last several weeks where
15 we actually talked it through and figured out where did they --
16 where are their real concerns.

17 The bottom line is, I think that we have a process
18 that we talked through last night. I have to get some
19 information to Mr. Ostfeld that he asked for, which I've
20 already checked with MSP's counsel, and it sounds like it's not
21 going to be a problem. It's just maybe how it gets explained
22 or what it is. And apparently it's a lot of data and things
23 like that. But it sounds like it's going to be satisfactory to
24 the defense.

25 The only issue that may remain once we're done

1 talking may be whether or to what extent the consideration paid
2 for the assignments is told to the jury and what, if anything,
3 Your Honor would tell the jury.

4 I don't think you need to get to that yet because I
5 would think you'd want to know what, if any, dispute remains.
6 I'm very optimistic and confident that will be potentially the
7 only issue that remains from this assignment issue when we're
8 done.

9 CHIEF JUDGE BUMB: Well, let me just shortcut it. So
10 I think there should be a stipulation that, you know, once the
11 parties are satisfied that there was consideration paid, I
12 think the amount of consideration paid is not relevant to the
13 jury. I think it's relevant to this Court's finding of
14 standing. I'm not going to let it go to the jury even if you
15 folks agree to it, because what I'm not going to have, you
16 know, is argument by the defendants like can you believe it, I
17 mean they bought the claim for this amount of money. I'm just
18 not going to do that.

19 MR. SLATER: Okay.

20 CHIEF JUDGE BUMB: So you folks either work it out or
21 I'll work it out for you.

22 MR. SLATER: No, that's helpful. And I think the
23 rest of it we're going to be able to talk through and figure
24 out.

25 CHIEF JUDGE BUMB: Okay. All right. Let's see.

1 That's that issue.

2 Okay. The next one I think Judge Vanaskie's working
3 on.

4 So the plaintiffs are requesting to add a breach of
5 express warranty subclass. I am, you know...

6 MR. SLATER: Probably not the right day to ask.

7 CHIEF JUDGE BUMB: Yeah. Denied. I am not adding
8 any more, no. The time has long passed. I mean, we are where
9 we are, folks, and that's it. There's just no way. I think
10 it's -- no, not doing it.

11 Okay. In limines. Let's see, deposition
12 designations, sanctions we talked about.

13 I don't understand what this introducing testimony of
14 the corporate pharmacy and wholesaler witness is. What is all
15 of that about?

16 MR. STANOCH: Your Honor, David Stanoch for
17 plaintiffs.

18 CHIEF JUDGE BUMB: Yeah.

19 MR. STANOCH: We want to introduce fact testimony
20 from the retailers, very short testimony that we took in this
21 case of their 30(b)(6) witnesses, fact testimony.

22 CHIEF JUDGE BUMB: Uh-huh.

23 MR. STANOCH: And our position is that because the
24 retailers are not defendants in this trial, they don't really
25 have any basis to object to designations that we have of their

1 clients which they say cannot appear, that they're outside
2 subpoena power, et cetera, et cetera.

3 So number one is, this shouldn't be a hard issue,
4 Judge, that we deposed nonparties to this trial, the pharmacy
5 people, right?

6 CHIEF JUDGE BUMB: Okay.

7 MR. STANOCH: We want to play very concise
8 designations of them at trial, you know, we're talking a few
9 minutes each.

10 CHIEF JUDGE BUMB: What would they say?

11 MR. STANOCH: They're going to say they don't
12 knowingly sell unadulterated drugs.

13 CHIEF JUDGE BUMB: They what?

14 MR. STANOCH: That they do not knowingly sell
15 adulterated drugs, which I know, I know, Your Honor. But to
16 have all the same defendants saying that they have value and we
17 could have sold it and TPPs might have paid some amount of
18 money for a contaminated drug, this goes to that very point.
19 And the testimony was largely unobjected to when we took it.
20 It's not like Your Honor is going to have to go through a
21 spreadsheet.

22 CHIEF JUDGE BUMB: Don't you all just insult the
23 intelligence of a jury? I mean, honestly, is there anyone who
24 in any format would say, yeah, we knowingly sell adulterated
25 drugs? Is there anyone would who would ever testify to that?

1 MR. STANOCH: That's not my argument, Your Honor.
2 For years, and I'm not being pejorative, for years I've been
3 hearing argument back from the defendants about the value of
4 these drugs, it was just a little carcinogen --

5 CHIEF JUDGE BUMB: But they've never admitted to
6 knowingly selling adulterated drugs, at least I don't know that
7 they have.

8 MR. STANOCH: But the point is, you can't have it in
9 the stream of commerce. And we'll get into this a --

10 CHIEF JUDGE BUMB: I know. Everyone knows that.

11 MR. STANOCH: Well, they don't.

12 CHIEF JUDGE BUMB: Just call two witnesses. They'll
13 ask three minutes. That's it.

14 MR. STANOCH: Okay.

15 MS. LOCKARD: Your Honor, if I may be heard on that
16 on behalf of the defense.

17 So the defendants in this trial case have also moved
18 to exclude these witnesses in total for a number of reasons.

19 First of all, they've identified eight witnesses.
20 The testimony goes far beyond they never would have knowingly
21 sold this. They are asking them about adulteration. They're
22 asking them about cGMPs. They are asking the witnesses about
23 it being worthless.

24 CHIEF JUDGE BUMB: No. I just ruled, he can call --
25 two sentences, three sentences. Would you knowingly sell

1 adulterated drugs? "No."

2 MS. LOCKARD: We would stipulate to that. We don't
3 need to take up more time of this Court and the jury to have
4 videos played of these extraneous witnesses. The testimony,
5 which is going to be cumulative, it's also going to be -- it's
6 going to be misrepresentative. It's going to be confusing.
7 There is no place in this courtroom to have pharmacy witnesses
8 from CVS or Rite Aid or Optum come in and talk about their
9 interpretation of what drugs were recalled. It just doesn't
10 belong here. We can work on a stipulation that says the
11 pharmacies would not have knowingly sold adulterated product.

12 MR. STANOCH: Judge, this is an interesting --

13 CHIEF JUDGE BUMB: Mr. Slater said yes.

14 MR. STANOCH: This is an interesting offer. We could
15 discuss it perhaps in a meet and confer and report back to you.

16 CHIEF JUDGE BUMB: If not, then Judge Vanaskie's
17 listening, and you will work with him to have a stipulation, or
18 you will show him the deposition designations, and they will be
19 about as brief as they are.

20 MR. STANOCH: Very good, Your Honor.

21 MR. SLATER: And they will only go -- I'm not sure.
22 Maybe there's an old version, but we were only planning to play
23 the part about the adulteration, so maybe there's a
24 miscommunication. We can talk before this stipulation.

25 CHIEF JUDGE BUMB: Okay.

1 MS. LOCKARD: I'm just talking about what was
2 provided in the pretrial order, which is the most recent that's
3 been submitted to us.

4 CHIEF JUDGE BUMB: Okay. I think it got resolved.
5 Let me go to -- is Maggie Kong and Lin, are you
6 intending to call them?

7 MS. DAVIDSON: Yes, Your Honor, we are.

8 And if I may say, Your Honor, I just want to note
9 that we designated them as expert -- as fact witnesses and told
10 plaintiffs they were available for depositions in February.
11 Plaintiffs never asked us for deposition dates. So it's now
12 been seven months since we've informed plaintiffs that we want
13 to bring these two fact witnesses to trial.

14 MR. SLATER: Well --

15 CHIEF JUDGE BUMB: They don't really seem to be
16 adding anything to the case. What?

17 MR. SLATER: Yeah. I mean, I'm not -- I didn't
18 really want to get sidetracked on that question because we
19 objected to the testimony altogether, and we certainly were not
20 going to do a solid for the defense and go take their
21 depositions so they could then say, oh, now they're unavailable
22 and now we can use their deposition testimony when they pulled
23 these witnesses out of their hat.

24 We, I think, have very compelling arguments why
25 neither of these witnesses should be allowed to testify.

1 Maggie Kong, as we laid out in our brief, the defense
2 took the position when they were opposing our request to get
3 her custodial file that she basically knows nothing, did
4 nothing. Now they say, well, we want to bring her in to talk
5 about the recall and a bunch of really vague areas that they
6 listed. And from our perspective, they should live with what
7 they said and not do what we think they're trying to do, which
8 is to bring her in and say, well, I'm the assistant chief of
9 staff to Baohua Chen and let me tell you he didn't know
10 anything, he wasn't involved, he didn't do this.

11 My guess is that's where it's going, because I can't
12 figure out why else they would try to call a witness who they
13 told the Court in trying to get Judge Vanaskie to deny our
14 request for a custodial file that she did nothing relevant in
15 this case and knew nothing. So injecting her into the case at
16 this point when they took that position, we think she should
17 not be allowed to testify in this case.

18 CHIEF JUDGE BUMB: Okay. And what about Lin?

19 MR. SLATER: Lin has a very interesting issue as
20 well. Number one, his custodial file is vastly, vastly
21 inadequate, as we laid out in the brief.

22 His email -- his email which is a very important
23 document in this case wasn't even in his custodial file. He
24 had worked at the company for many years. The documents didn't
25 predate 2017. So that's number one; that they want to take a

1 witness for whom we have an obviously inadequate and incomplete
2 custodial file, put him on the stand, and then we don't have
3 the ability to actually know everything that he knew, and it
4 would be very prejudicial, number one.

5 Number two, the only reason that I could think of
6 that they would want to call him, because we know what Jucai Ge
7 said, she wanted to testify, and Your Honor's barred the
8 hearsay testimony, that he said, oh, you know, it was a poorly
9 written email, I didn't really mean that. So we're going to
10 now bring this witness in who has an absolutely inadequate
11 custodial file to come in and say that when the 30(b)(6)
12 witnesses who spoke for the company, including Min Li, his
13 boss, who received the email and went through the email during
14 his deposition and Min Li said this is what it says, you're
15 going to have Jinsheng Lin now say it doesn't say what our
16 corporate rep says it said. That would be very, very
17 prejudicial and I don't think should be allowed at all because
18 for obvious reasons.

19 Now the jury is going to say, wait, the company who
20 Min Li spoke for says it says this. And ZHP's own translation
21 of the email says what we are focused on, which is there's NDMA
22 in valsartan which is caused by the sodium nitrate quenching,
23 which is the root cause.

24 So for those reasons, it would be inappropriate to
25 let Jinsheng Lin now contradict their own translation, their

1 own 30(b)(6) testimony with an inadequate custodial file where
2 we would never have a fair opportunity to cross-examine him.

3 MS. DAVIDSON: Your Honor, plaintiffs want to make
4 this entire case about an email by Mr. Lin --

5 (Court reporter clarification.)

6 MS. DAVIDSON: Plaintiffs want to make this entire
7 case about an email by Mr. Lin. Plaintiffs made a choice not
8 to depose him. We don't know why. But he is the man who wrote
9 the email that they think is the "center" document in this
10 case. Obviously it's highly relevant to have that person here.
11 We offered him for deposition. No idea why plaintiffs refused.
12 But by refusing to take someone's deposition, plaintiffs can't
13 decide who we can bring to trial.

14 CHIEF JUDGE BUMB: Right. But if you misled them and
15 said that he doesn't have any custodial files or you misled
16 them and said Kong has no knowledge --

17 MS. DAVIDSON: There was no misleading, Your Honor.

18 CHIEF JUDGE BUMB: I'll let Judge Vanaskie decide it.

19 MR. SLATER: Fair enough.

20 CHIEF JUDGE BUMB: Refer it to him and he'll resolve
21 the dispute.

22 But my preliminary view is, is that if somehow the
23 defendants lulled the plaintiffs or misled them or whatever,
24 they're not going to profit from that. So we'll see.
25 Judge Vanaskie will sort that out.

1 MS. DAVIDSON: Your Honor, I do just want to say, if
2 I may --

3 CHIEF JUDGE BUMB: Yes.

4 MS. DAVIDSON: -- that there was no accusation of any
5 lulling or any misrepresenting. Ms. Kong's files were
6 produced --

7 CHIEF JUDGE BUMB: No; there is an accusation of
8 that.

9 MS. DAVIDSON: Well, it's not on the record, Your
10 Honor.

11 CHIEF JUDGE BUMB: Well, that's what their brief
12 said.

13 MR. SLATER: Yeah. That was the -- ZHP's brief,
14 August 13, 2021, said that as a member of the president's
15 staff -- I'm reading from their brief -- she has no direct role
16 in the development, manufacturing, testing or sale of
17 valsartan, nor does she have any regulatory responsibilities at
18 the company.

19 CHIEF JUDGE BUMB: Right. That's what I'm
20 remembering. And that's on the basis why you don't want the
21 testimony to come in. Yeah.

22 MS. DAVIDSON: Your Honor, Judge Vanaskie ordered
23 that Ms. Kong's files be produced. Her files were produced.
24 And therefore plaintiffs' argument, to the extent they tried to
25 argue in their briefing that it's a judicial estoppel issue,

1 judicial estoppel only applies if you actually win an argument.
2 We did not win the argument.

3 MR. SLATER: That's not true.

4 MS. DAVIDSON: Her custodial files were produced.
5 And so there's no reason why she shouldn't be allowed to
6 testify at trial. Like, the company has a right to bring to
7 trial witnesses that the company chooses. The plaintiffs don't
8 get to choose which witnesses a defendant brings to trial from
9 his corporation.

10 So we informed plaintiffs in February that these two
11 witnesses, we would like to bring them to trial, offered them
12 for deposition. Judge Vanaskie also found no spoliation or any
13 inappropriate -- any inappropriate conduct with respect to
14 Mr. Lin's custodial files.

15 Mr. Lin did not work directly on valsartan, and
16 that's why there weren't valsartan documents, but it's --

17 CHIEF JUDGE BUMB: You folks are not agreeing on what
18 transpired. Judge Vanaskie will lay it out.

19 MR. SLATER: Fair enough, Your Honor. Thank you.

20 CHIEF JUDGE BUMB: All right. I'm just going down
21 the plaintiffs'. The punitive we've discussed. Number four
22 has been worked out.

23 Five, six, seven. Retailer defendants should not be
24 permitted to object to testimony as they are not parties to the
25 trial. That's what we just discussed?

1 MR. SLATER: Correct.

2 CHIEF JUDGE BUMB: Okay. Nine, plaintiffs...

3 MR. SLATER: This is an issue that's --

4 CHIEF JUDGE BUMB: For the trial?

5 MR. SLATER: That we've discussed and that's tied up
6 in the trial length issue that Your Honor wanted to put to the
7 side.

8 CHIEF JUDGE BUMB: All right. I'll come back to
9 that.

10 Number 10, Dr. Hecht and other experts should not be
11 subjected to unreasonable questioning on cross-examination.

12 I don't know. Is there any court that would say that
13 you can have unreasonable questioning on cross-examination?

14 MR. SLATER: No. I mean, the context -- the
15 substance of it, as laid out in our brief, is that we were
16 really focused on two issues. One was more generic, and I'm
17 not sure what Your Honor's process is at trial. Judge Kugler's
18 process was that we would actually read the qualifications to
19 the jury because the witnesses had already been found qualified
20 and then we would go into the substantive testimony. So it was
21 our sense that even despite that, the defense was still going
22 to seek to cross on qualifications. So it didn't seem to make
23 sense.

24 But more specifically with Dr. Hecht, as we laid out
25 in our brief, he worked at a place called the American Health

1 Foundation and did some very important research there in the
2 1970s and then left. After he left, people that were there
3 were indicted apparently for stealing research funds or
4 something. I'm paraphrasing. I don't have the exact -- it's
5 in the brief. So we just want to make sure they're not going
6 to start to cross Dr. Hecht because he was questioned in his
7 deposition about this and spill out to the jury, well, that
8 foundation you worked at in the '70s, weren't people indicted
9 there, to try to make him look like he worked at a criminal
10 organization, which would be completely obviously unfair,
11 irrelevant, and a 403 issue.

12 MS. ROSE: I did not want to interrupt Mr. Slater,
13 but we do not intend to enter any of that evidence. We wrote a
14 brief actually explaining that in response to plaintiffs' trial
15 brief. And Judge Kugler decided at the time that he didn't
16 want to see any more briefing, so I don't think that brief was
17 considered. I'm not sure if it's even still on the docket.
18 But we had filed the brief which Mr. Slater received.

19 CHIEF JUDGE BUMB: See how reasonable they are.

20 MR. SLATER: The more that -- hey, you know, Judge,
21 when you talk, you work things out, so...

22 CHIEF JUDGE BUMB: Exactly.

23 MR. SLATER: That's great.

24 MS. ROSE: But, Your Honor, may I be heard on the
25 overall issue of the questioning of the qualifications?

1 Plaintiffs seem to be requesting or suggesting that
2 because the Court did not exclude Dr. Hecht on a qualifications
3 argument, it therefore found that he is eminently qualified and
4 can't be questioned on his qualifications, which is not the law
5 anywhere. A finding on *Daubert* that an expert meets the
6 threshold qualifications does not mean that they can't be
7 cross-examined. And in fact, it's to the opposite.

8 I believe in plaintiffs' brief where we were briefing
9 the issue of Dr. Hecht they said over and over again this is an
10 issue for cross-examination, like these *Daubert* arguments --

11 CHIEF JUDGE BUMB: So there's not going to be a
12 stipulation as to the qualifications on these witnesses? Some
13 there are, some there aren't. Is that what you're saying to
14 me?

15 MR. SLATER: Yeah. I can say from our perspective
16 this brief was based on our understanding of how Judge Kugler
17 was going to conduct the trial.

18 CHIEF JUDGE BUMB: Well, I'll tell you how I will
19 conduct it.

20 MR. SLATER: Thank you.

21 CHIEF JUDGE BUMB: But are you saying to me that
22 there's not going to be a stipulation or you're going to want
23 an opportunity to voir dire?

24 MS. ROSE: Yeah. We would like an opportunity to
25 cross any expert on any issue that --

1 CHIEF JUDGE BUMB: On qualifications. It's a voir
2 dire.

3 MS. ROSE: Oh, yes, Your Honor, we would like to.

4 CHIEF JUDGE BUMB: So the way it will work is you'll
5 introduce the qualifications, you'll move him or her as an
6 expert, and if there is any voir dire at that time for the
7 qualifications, they'll voir dire then. And then I'll make a
8 ruling that the witness is or isn't qualified.

9 MR. SLATER: Fair enough.

10 Will we question the witness on their qualifications
11 or will we read a statement in the court?

12 CHIEF JUDGE BUMB: It would be my preference that you
13 just sort of, you know, not take a whole lot of time on these
14 qualifications, that, you know, I presume that all of your
15 experts, just like Professor Conti, are eminently qualified.
16 And in my experience of, you know, being here a million years,
17 jurors just don't want to hear about every publication the
18 expert wrote.

19 MR. SLATER: Fair enough.

20 CHIEF JUDGE BUMB: They just don't. And so, you
21 know, if there's a stipulation that their CVs can go into
22 evidence, that's how I prefer it, because I think that helps
23 move things along. If there's not a stipulation, I can't force
24 it, but I would just ask that the parties not spend a ton of
25 time on the qualifications. But I'm not going to prevent the

1 defendants from voir diring on qualifications and then I'll
2 make my ruling.

3 MR. SLATER: Understood.

4 CHIEF JUDGE BUMB: Okay.

5 MS. ROSE: Thank you, Your Honor.

6 CHIEF JUDGE BUMB: Translating mechanism we talked
7 about.

8 MSP assignment we talked about.

9 Okay. Judge Vanaskie's working on the deposition
10 designations.

11 We worked on number 14, to preclude the testimony of
12 wholesaler and retailer witnesses, and then the next issue.

13 All right. Travel plans, trial scheduling and
14 planning and jury selection is where we're at.

15 MR. SLATER: Yes, Your Honor. This is --

16 CHIEF JUDGE BUMB: Wait. Hang on one second, because
17 you have more here. Let me just make sure. Because I think
18 that might be -- yeah, I think we've covered everything except
19 for trial management.

20 Can we take a five-minute break and we'll be back?
21 Yeah?

22 MR. SLATER: Of course.

23 THE COURTROOM DEPUTY: All rise.

24 (Recess was taken at 3:25 p.m. until 3:43 p.m.)

25 THE COURTROOM DEPUTY: All rise.

1 CHIEF JUDGE BUMB: Okay. You can have a seat. Thank
2 you.

3 So before we get to the trial, because my brain won't
4 stop thinking, I just need better briefing from the parties on
5 the issue of the damages, because I feel like I'm going around
6 in circles sometimes. Maybe you all feel the same way about
7 it, but -- and maybe it's because it's in the pharmaceutical
8 context and that matters, but I just don't understand why it
9 should be. And I'm going to pose some hypotheticals and then
10 you folks are going to brief the issue.

11 The plaintiffs take the position that from day one
12 these drugs were adulterated and therefore they had no value.
13 The defendants take the position of -- well, let me back up for
14 a second.

15 The first thing I want to pin the parties down is,
16 what are the express warranties that the plaintiff is suing on?
17 Because there's a disconnect, it seems to me, between what the
18 express warranty is. The plaintiffs are saying you sold -- you
19 said that you would -- that you would sell us an Orange Book
20 drug. And the defendants I'm hearing are saying, no, the
21 warranty to the TPPs was we will sell you a drug at a reduced
22 cost. So there's even a disconnect amongst the parties as to
23 what warranties, warranty or warranties are you suing on. So
24 let's clear that up.

25 Then the second issue is, assuming that the warranty

1 is that the drug that is being sold is valsartan, Orange Book
2 drug, et cetera, compliant, what are the damages?

3 The defendants want to say, well, you know, it was
4 therapeutically effective and so the damages should be reduced.
5 But I can go through, you know, an analogy where that argument
6 falls. You know, if I -- if I -- if I buy a Coach bag, I think
7 it's a Coach bag and I keep it for ten years and then it turns
8 out I learned that it's not a Coach bag and it's bogus, I mean
9 is the argument from the defendant: Well, so what? You had a
10 pocketbook. That doesn't sound right to me.

11 But then I get, in the case that I gave earlier, if
12 the defendants are selling placebos and it turns out that it
13 was a placebo, the defendants aren't going to make the
14 argument, well, so what? You got a value. At least you
15 thought you were getting a good drug. I mean, they're not
16 going to make that argument. I don't think you are.

17 So you folks are going to have to do some work to
18 help me or walk through this. So the first is, what are the
19 warranties that the plaintiff is suing on. Let's hear from
20 that, okay, number one.

21 And number two, case law that tells me that if that
22 express warranty is violated, then the damages are from the
23 beginning to the end and that the defendants should not be
24 permitted to say, well, you got the benefit of the bargain
25 because...

1 You know, I would be very curious, and, you know, I
2 often think about the *Volkswagen* case. I mean it was a
3 settlement, there was no issue. But there the car drove fine.
4 There the car got 50 miles to the gallon or whatever it was.
5 It just wasn't something clean. Clean something. And I think
6 the Court found that that was an express warranty violation.

7 So I just need you folks to do some more work on
8 that, because I just -- I'm going around in circles about it,
9 okay. Five pages. And the sooner you can get them to me, the
10 better because it will help inform my decisions on these
11 experts.

12 MS. ALLON: Your Honor, can I just ask a question
13 about that?

14 CHIEF JUDGE BUMB: Five pages.

15 MS. ALLON: And it's about the hearing tomorrow.

16 CHIEF JUDGE BUMB: Yeah.

17 MS. ALLON: So tomorrow we're supposed to hear from
18 Dr. Stiroh.

19 CHIEF JUDGE BUMB: Yeah.

20 MS. ALLON: We're supposed to have argument on the
21 *Daubert* and on Motion in Limine 16, right, which is about this
22 alternative drugs issue. And so I'm just trying to understand
23 how that will interact with the briefing. The plaintiffs
24 essentially are going to make more arguments about more things
25 from Dr. Stiroh that should be excluded. I'd certainly like to

1 have the benefit of seeing those papers, but we can also
2 proceed based on the papers we do have tomorrow. Whatever
3 would be most helpful to the Court.

4 CHIEF JUDGE BUMB: Well, you already have Dr. Stiroh.
5 I can only sit until 12:30 tomorrow, so we have to get Dr.
6 Stiroh on and off. And you have -- him, right. It's a him?

7 MS. ALLON: Her.

8 CHIEF JUDGE BUMB: Her?

9 MS. ALLON: Yeah.

10 MR. SLATER: Is she still here? She was here all
11 day.

12 CHIEF JUDGE BUMB: You have her available.

13 MS. ALLON: Yeah, no. She's available tomorrow.

14 CHIEF JUDGE BUMB: It just seems to me we should
15 proceed.

16 MR. SLATER: We would like to proceed.

17 CHIEF JUDGE BUMB: I do sort of -- well, I don't
18 know. Maybe this is -- I just sort of feel everything is a
19 moving target here, and there's just not a whole lot of
20 clarity. And I'm --

21 MS. ALLON: Well, maybe we should do this, Your
22 Honor: I think Dr. Stiroh is available, so we should have her
23 examination. I'm just wondering about the argument. We're
24 prepared to argue it. It's not a question, but I don't want to
25 just --

1 CHIEF JUDGE BUMB: I need to see case law on this,
2 because --

3 MS. ALLON: Right. So should we defer --

4 CHIEF JUDGE BUMB: Excuse me.

5 Because the arguments appeal to me from both sides.
6 But I don't have good clarity on what the law is. And if at
7 the end of the day you all come back and say in a
8 pharmaceutical context this is the first case of its kind, then
9 so be it. I'll make the call as I see it. I just find that
10 very hard to believe that there are not analogous cases out
11 there where courts have struggled with this issue, or maybe not
12 struggled like I am.

13 You had a question.

14 MS. ALLON: I was going to ask if we should defer
15 argument on the -- we will have the testimony from Dr. Stiroh.
16 But do you want to hear argument on the 702 and on MIL 16, or
17 should we defer that until we have the supplemental briefing?

18 CHIEF JUDGE BUMB: MIL 16 is what?

19 MS. ALLON: Alternative products.

20 CHIEF JUDGE BUMB: Oh, yeah.

21 MR. SLATER: We'd like to proceed as scheduled.
22 Obviously if Your Honor hears the argument, you'll have the
23 briefing, you'll see the law and --

24 CHIEF JUDGE BUMB: I really want the briefing,
25 though. I mean, I could be up here creating error.

1 MR. SLATER: We do have --

2 CHIEF JUDGE BUMB: Wouldn't that be awful?

3 MR. SLATER: We do have briefs on this issue, though,
4 we just filed, right?

5 CHIEF JUDGE BUMB: I'm sorry. I don't find them -- I
6 did not find them to be helpful.

7 MR. DAVIS: We'll go --

8 CHIEF JUDGE BUMB: And it's not meant to be a
9 criticism. It's just you folks have got to drill down more.
10 You have to drill down more into these cases. You have to
11 drill down and help me understand your arguments.

12 I did not find -- you know, I found the RICO cases to
13 be distinguishable and some of the other cases to be
14 distinguishable. I'm not sure the *Blue Cross* case helped me.

15 And I may want to take another look at my -- what
16 I've said about doctor -- professor. I thought Ph.D.s were
17 doctors, but I'll remember that, Professor Conti's, not
18 physicians, but doctors, whatever.

19 I may have to revisit that, too.

20 Okay. All right. Talk about trial. So the sooner
21 you folks can get that to me, I would very much appreciate it,
22 since I'm not going to stop thinking about it until I resolve
23 it in my head.

24 Trial.

25 MR. SLATER: The bottom line, Your Honor, is that we

1 don't -- we've been through the witnesses. We've been cutting
2 video for the witnesses that definitely are not being brought
3 live. We've been cutting video for the witnesses that the
4 defense has offered to bring live, and we've looked at all our
5 experts and looked at all the witnesses we have to call, and
6 the bottom line analysis that we have is that to try this case
7 for the plaintiffs, if we start November 4, we will get done
8 somewhere between I believe, if I have it right that the
9 26th is a Wednesday, somewhere between the 24th and the 26th of
10 November. That's with the 9:00 to 2:00, with the 30 minutes of
11 breaks, taking everything into account.

12 That's how long we would need. I could go through
13 all this with Your Honor. I can tell you I have an analysis
14 witness by witness.

15 CHIEF JUDGE BUMB: So what do you want me to do,
16 because some of you have conflicts in December you say?

17 MR. SLATER: Well, we're -- the plaintiffs are ready
18 to try the case from when Your Honor says to start --

19 CHIEF JUDGE BUMB: Yeah.

20 MR. SLATER: -- until we finish like any other trial.

21 CHIEF JUDGE BUMB: Yeah.

22 MR. SLATER: We understand the defense has some
23 conflicts and some other issues where it's up in the air.

24 I can say, for example --

25 CHIEF JUDGE BUMB: Well, if it's not witness

1 conflicts, then counsel can be, you know, interchanged. I'm
2 not going to not do a case because counsel is not available.
3 They'll have to -- you all -- you know, you all have ten
4 lawyers for one.

5 MR. SLATER: So if that's -- and understanding that,
6 then I don't see any reason why we shouldn't be able to. We're
7 not sure how much time the defense has. Certainly not trying
8 to stick that on the defense right now to say maybe they're
9 ready or not for how long they need. But we have three
10 defendants. We obviously have to put in a case against three
11 large companies. They're all going to want their opportunity
12 to defend. I don't know how long they need, but from our
13 perspective, if we can start November 4, try the case to
14 conclusion in December and obviously we need to talk about that
15 and understand how much time each of the three defendants
16 needs, then that's probably the most feasible thing.

17 My guess is Your Honor doesn't want to move the trial
18 to start earlier in October because I think Your Honor said you
19 had other things in October. So obviously it's Your Honor's
20 discretion. But the easiest --

21 CHIEF JUDGE BUMB: If I don't try this case in
22 November, I'm not available until next summer.

23 MR. SLATER: We would like to start November 4, and
24 we would like to finish in December when the case finishes and
25 get it done in December. And that's, to us, the best way to do

1 it. The plaintiffs were available. We have multiple counsel
2 here. We'll get our case in before Thanksgiving. The defense
3 would pick up right after Thanksgiving, it looks like, or maybe
4 even a few days before depending on how things flow and some
5 decisions that may get made and some things we can work out,
6 and the defense can finish their case and we get done in
7 December.

8 And because of the gravity of what this case means to
9 this litigation after all these years, we think that's probably
10 the most reasonable and efficient way to do it so each of the
11 parties can put on the case that they think they need to put on
12 and Your Honor can get a fulsome look at the facts and we can
13 try the case to conclusion.

14 CHIEF JUDGE BUMB: Okay. Well, we will.

15 MS. ALLON: Your Honor, I've had two conversations
16 with the plaintiffs about this topic, and on both of those
17 occasions I asked them how many witnesses do you have? What
18 are the hours? What are we talking about, right? Because we
19 can all once we know what the hours look like, then the Court
20 can either set time limits or not, but we can accommodate them.
21 I've got no feedback from them. So at no point were they
22 willing to engage on these are the actual witnesses. We've
23 emailed them, these are the witnesses we're bringing live. Do
24 you want them in your case-in-chief? No response.

25 CHIEF JUDGE BUMB: Why?

1 MS. ALLON: So instead what we have is --

2 CHIEF JUDGE BUMB: Why?

3 MR. SLATER: That's -- I'll be happy --

4 MS. ALLON: Can I just finish?

5 MR. SLATER: Oh, I'm sorry. I thought you were
6 asking me a question.

7 CHIEF JUDGE BUMB: No, no, I don't want you to
8 finish. I want to know why.

9 MR. SLATER: My understanding is the only counsel
10 that Ms. Allon has spoken to is counsel who is handling the
11 Torrent part of the case. I've never had a --

12 MS. ALLON: I spoke to your colleague who said she
13 was calling on your behalf.

14 MR. SLATER: I'm sorry.

15 CHIEF JUDGE BUMB: Okay. Listen, you're not going to
16 leave today until you folks have mapped out the witnesses
17 today.

18 MR. SLATER: Yeah. I have the whole list here. But
19 I've never been asked, and I'm running the ZHP part of the
20 case. Mr. Stanoch and Mr. Honik have been doing the Teva part.

21 CHIEF JUDGE BUMB: Okay. Here's where I -- you
22 ready.

23 After today you will all sit down and work it
24 through. But what's your --

25 MR. SLATER: I can also say --

1 MS. ALLON: Well, so my concern is --

2 MR. SLATER: I thought it was agreed that it was
3 going to be the two witnesses you proposed.

4 CHIEF JUDGE BUMB: Let her finish.

5 MS. ALLON: So my concern is that a year ago we all
6 told Judge Kugler how long we thought this case was going to
7 take, and then several months ago we talked to Your Honor about
8 how long this case was going to take. And at no point in any
9 of those time periods did the plaintiffs say that 80 hours I
10 think is what we ended up with is not enough time.

11 I have a conflict. I can't try the case through
12 December. And I have been counsel to Torrent for four years,
13 since this case was filed, and I would like to try this case to
14 verdict. And I had no question that I would be able to do that
15 until I saw the letter from Mr. Slater saying, all of a sudden,
16 that he couldn't try the case in the time that was allotted by
17 the Court.

18 CHIEF JUDGE BUMB: Well, here's what I'm going to
19 say, is that I want you folks to sit and meet. My experience
20 is when attorneys, and for those of you who have tried cases in
21 front of me, and there are some of you out there, that when
22 attorneys tell me it's a four-week trial, I cut it in half and
23 I'm usually right. And so I always feel as if it's never as
24 long as the parties say it is, particularly not in my courtroom
25 where I run a pretty -- a pretty, you know, stay on schedule.

1 MS. ALLON: Well, so I'm happy to meet and confer
2 with the plaintiffs. What I thought would happen is, we have
3 an amount of hours. By the way, there's a disagreement between
4 the parties about how those hours will be allocated. So the
5 Court has to resolve that. Is it equal or is it not equal?
6 And then once we know the hours, that's it, you get your time;
7 and when your time is up, the trial is up.

8 CHIEF JUDGE BUMB: How can I best be of assistance?
9 Do you folks want me to sit here and go through each witness
10 and map it all out? I'm -- I was going to say I'm happy to do
11 that. I'm not happy to do it, but I will do it. You folks
12 should be able to work this out.

13 I will say that this should not be more than a
14 four-week trial. I don't see the issues to be that
15 complicated. But, again, I said that yesterday, I take the
16 bench this morning and you folks can't even agree what the
17 claims are.

18 So I will say that if I have another day like today
19 where you can't even agree what the claims are and you can't
20 even agree that the law is what the law is or whatever, I will
21 adjourn the trial and we'll try it next summer. Because I'm
22 just not going to have this back and forth during the trial.
23 It will be so unmanageable, and it won't get done in four
24 weeks. So that's why I'm asking for this five-page submission.
25 I'm going to just try to start honing it in and figuring it out

1 what the claims are. It just -- it doesn't to me seem to be
2 that complicated of a trial.

3 MR. SLATER: Can I tell you where I think a lot of
4 the trial length is coming from?

5 CHIEF JUDGE BUMB: Yeah.

6 MR. SLATER: When we spoke to Judge Kugler way back
7 about the length of the trial, we didn't agree to three and a
8 half, four weeks. It was four weeks that Judge Kugler said.
9 We said if you rule in certain ways on certain of these
10 motions, the dispositive motions on adulteration, cGMP, and
11 those issues don't have to be tried and some other things, and
12 we also were assuming we were going to use the videos, which
13 then we know exactly how long the videos take as opposed to how
14 long is it going to take to do a live presentation where it
15 always takes longer, then there's three crosses from the
16 defense, et cetera. That was not factored into our analysis,
17 but we said this is subject to what else may happen.

18 Now that we've learned what we've learned, we do have
19 a list of witnesses. And, again, I told Your Honor we've cut
20 down videos enormously in order to try to convince Your Honor
21 to let us use some of the videos for some of the witnesses,
22 because we took to heart what you said, and we understand what
23 you're looking to do. But in terms of getting the case done,
24 the video -- I can give you an example.

25 We have Min Li. Min Li is a very important 30(b)(6)

1 witness for ZHP. I have his video now cut down, and it's being
2 sent over to my friend, Ms. Rose, very shortly, an hour and 38
3 minutes. That is a very important witness who covers an
4 enormous amount.

5 If he goes on -- that's an hour and 38 minutes, give
6 or take, depending on where we end up with some objections. He
7 goes on live, he's going to be at least a day to two days
8 because it's going to take a lot of time to get through with
9 him. You're going to have all the defendants questioning him.
10 There's going to be the cross that's going to go back and
11 forth. So that's an example of how the video --

12 CHIEF JUDGE BUMB: So if you present -- sorry to
13 interrupt.

14 MR. SLATER: You never have to apologize to me,
15 Judge.

16 CHIEF JUDGE BUMB: If you present the video
17 deposition or that's what your ask is, then I'm going to spend,
18 you know, two, three days going back and forth about the
19 objections and the cross-designations, right?

20 MR. SLATER: I don't think so because of this: The
21 way that we have things stacked up right now, we have I think
22 one witness we're ready to talk to Judge Vanaskie and another
23 one I think we're very close to, and there could be a few
24 others that could be put in. We've actually worked very well.
25 Myself and Ms. Rose have been hammering this out for a long

1 time now. There are certain systemic objections, like the one
2 that you saw before about whether or not when you ask a witness
3 isn't it true that this was contaminated with NDMA and the
4 witness says yes, but nobody knew and the FDA didn't know, et
5 cetera, et cetera, once Judge Vanaskie rules whether or not the
6 answer stops at the yes and the talking point is in or out,
7 then we're going to know. We're going to go back to all the
8 other videos and we're going to know, okay, we're not going to
9 keep bringing Judge Vanaskie the same issue, and so on and so
10 forth because that's what we would have to do. So I don't
11 think it's going to be that kind of battle.

12 I can tell you in the trials I've done with a lot of
13 video, we do this in advance, we act reasonably, once we get
14 the guidance from the Court on a number of objections,
15 everybody knows, okay, the same thing is going to apply here,
16 the same thing is going to apply there. And we work through
17 it.

18 There's not an unmanageable amount of objections. A
19 lot of them you've already resolved, frankly, Your Honor, with
20 your MIL rulings. There's a few that we obviously have to
21 figure out what a few of them are, but they're being held to
22 the side, so I don't really think that's going to be a major
23 problem.

24 In terms of time-saving for the Court, it's so much
25 more efficient, and that's how we, frankly, prepared this case

1 from years ago when we were taking these depositions. And I
2 could go through.

3 I can tell you, some of the other witnesses that the
4 defense has said, well, we have them ready to bring live, I can
5 give you some of the names. John Iozzia, his video is 24
6 minutes. Linda Lin, with a translator, is 20 minutes now.
7 Lijie Wang, who is also available, 16-minute videos.

8 So what we've -- we understand what Your Honor wants,
9 and we understand that if we're going to play video, we're not
10 going to play days of video for each witness. Nobody wants to
11 do that.

12 And I could go through this. I have witnesses five
13 minutes, eight minutes, three minutes, 25 minutes. I mean,
14 we're cutting these down to the point where boom, boom.
15 There's a few witnesses that are a little longer.

16 Hai Wang, I mentioned him earlier. Hai Wang, as of
17 right now, and it's not done being cut, is an
18 hour-and-43-minute video. We may decide to bring him live
19 anyway. But if we play an hour, let's say it's an hour and 30,
20 hour and 40 minutes, again, he's another witness that will be
21 longer on the stand. So, again, we can make this more
22 efficient.

23 And I don't think the objections frankly, I
24 understand the reticence of the Court, but it's a necessary
25 part. We're obviously going to have to work as efficiently as

1 possible.

2 I can't imagine anyone's going to bring Judge
3 Vanaskie the same objection six or seven times and try to say,
4 well, you know, have you changed your mind on that issue.
5 We're going to take the guidance and we're going to follow the
6 guidance, and all of a sudden the amount of disputes is going
7 to go like this. And some of them are real, legitimate
8 disputes. And think about it, the witness is on the stand, you
9 have to have a sidebar, you have to talk about it, you have to
10 deal with a translating issue. You have to deal with all this.
11 That takes time, and the Court has to deal with it as opposed
12 to it's done in advance. And when we're opening for witnesses
13 where the videos are done, everybody knows exactly what the
14 testimony is going to be, they know exactly which exhibits are
15 coming in, everybody has exchanged the exhibits. We know
16 what's being admitted.

17 CHIEF JUDGE BUMB: You're making your point.

18 Do you agree? Does that help you?

19 MS. ALLON: I agree that in the instances where
20 deposition video will be played, that will be a smooth process.
21 I do not agree that it will help the efficiency of this trial
22 to allow the plaintiffs to play video for witnesses who are
23 coming live. That would double the time, not half it.

24 So I agree with Mr. Slater that there will be video
25 testimony for unavailable witnesses that the parties agree on,

1 and that will be a smooth process.

2 But to the extent Mr. Slater is suggesting --

3 CHIEF JUDGE BUMB: Well, here's my ruling: Try to
4 work it out so that this case can be tried in four weeks, as we
5 originally planned.

6 To the extent that means that you would be playing
7 videotape depositions instead of bringing the live witness,
8 then so be it.

9 If the defendants -- so you're going to work that
10 out. If the defendants still want to call a live witness, then
11 they control the length of the trial because they will be
12 extending it by calling a live witness that has already been
13 played by video. That's the only fair way that I think that I
14 can handle it, okay?

15 So try to work it out. Try to work it out with
16 videotape witnesses. But what I'm not going to do is say,
17 well, I'm going to force the parties to now all present live
18 witnesses because that might extend the trial unnecessarily.
19 And so but I'm not going to preclude the defendants from
20 calling live witnesses. They have that right. But they'll
21 have to tailor it in a limited fashion because the videotape
22 deposition's already been played.

23 MS. ALLON: But, Your Honor, we did talk about this
24 at the last hearing, and so there are witnesses that the
25 defense has offered to make available in Mr. Slater's case.

1 CHIEF JUDGE BUMB: Yeah, right. But now he's telling
2 me that if he does that, it will unnecessarily delay the trial,
3 go into December. You're not available. I'm trying to balance
4 the equities.

5 MS. ALLON: Well, but, Your Honor, I don't see how
6 having a witness once will delay a trial more than having a
7 video and then a witness live.

8 CHIEF JUDGE BUMB: Because he's representing to me
9 that the reason he needs that witness is very limited, 24
10 minutes, 8 minutes' long, 10 minutes' long. That's his case.
11 And so what I'm saying is if the plaintiff can get their case
12 in in two weeks, I'll turn it over to the defense to get their
13 case in. And if it gets extended into December, I can't do
14 anything about it. We're going to go to conclusion.

15 MS. ALLON: Well, but --

16 CHIEF JUDGE BUMB: I don't -- I don't think it's fair
17 to say, well, we have to get this trial done in four weeks and
18 Mr. Slater says he's trying to accommodate and get that done
19 and then the defendants say, yeah, but if you force him to call
20 a live witness when he's telling me, but that's just going to
21 extend the trial.

22 MS. ALLON: Well, Your Honor, two things. That time
23 wouldn't -- like what I think the easiest way to resolve this
24 difficulty is, Mr. Slater has represented to the Court many
25 times that at the outside, the longest this trial will take is

1 100 hours. That's five weeks. That's what he told the Court.
2 For a year we've all been operating under that assumption.

3 Now he's telling the Court that he needs that 100
4 hours for his case-in-chief. So that is a dramatic departure
5 from everything he's ever told us.

6 What I think would be helpful is for the Court to
7 give us a number of hours and then each party has the hours
8 they have. If he wants to play video in his hours, fine. If I
9 want to bring live witnesses in my hours, fine. But the
10 defense doesn't have to sit around worrying that he's going to
11 take up two-thirds of the trial time because we have a chess
12 clock.

13 CHIEF JUDGE BUMB: No; I can do that.

14 MS. ALLON: So that I think would help the parties
15 most. It would ensure that we stay on track. And frankly, it
16 would ensure that all three lead counsel for the defendants who
17 all have conflicts in December could accommodate this trial. I
18 think that's all we need and then we won't have a problem.

19 MR. SLATER: I'm not --

20 CHIEF JUDGE BUMB: And that way if you want to
21 proceed by video, proceed by video.

22 MR. SLATER: Thank you.

23 And I'm not sure when I said 100 hours. All I can
24 reflect back is when we talked about the length of the trial
25 last time, it was a different world. And what I was going to

1 start to say before, and I sidetracked myself, is the reason
2 that it's a lot longer than it otherwise would be and Your
3 Honor looks at the claims and I think fairly said, well, these
4 sound straightforward, the litigation over the cGMP issues
5 which is one of the bases to establish adulteration, if you
6 violate cGMPs, it's adulterated, is a huge chunk of the
7 testimony that's going to be coming in.

8 If we had won that issue and either adulteration
9 and/or cGMP had been found as a matter of law, the violations,
10 you're talking about a much narrower trial. And also there
11 were summary judgment motions, et cetera, MILs on that, so it
12 was all subject to what happens later, and it didn't pan out.
13 We didn't win summary judgment on those issues. So now there's
14 a lot of testimony about what are the cGMP obligations, what
15 are the guidances, what are the regulations, what did your SOPs
16 say, who was responsible to do what, because we have to make
17 sure we cover that base. Even though we feel very confident
18 that the FDA findings is very persuasive, we also have to -- we
19 want to show the jury -- because we know a lot more than the
20 FDA did. We have a lot more information about why cGMP was
21 violated than they did.

22 CHIEF JUDGE BUMB: Okay.

23 MR. SLATER: So I just wanted you to know, that's
24 where a big part of the time is going to go.

25 CHIEF JUDGE BUMB: Okay. So you folks come up,

1 you'll each have a limited number of hours. Work it out.
2 You'll each monitor it. And if you want to present by video,
3 present by video in a way that this case is tried to conclusion
4 in the time frame that I've allotted, which is, what, four
5 weeks, five weeks? I don't remember.

6 MS. ALLON: It was 80 hours. It was four weeks.

7 CHIEF JUDGE BUMB: Okay. Eighty hours.

8 MS. LOCKARD: If I may speak up on this issue with
9 the deposition designations, I understand from the Court's
10 ruling at the last CMC that if there were witnesses who would
11 be played by video, that those witnesses' videos would be
12 played one time. And so we would be entitled, the defense, to
13 put on our affirmative designations following plaintiffs'
14 designations; that they would be played in chronological order
15 so we have a video of a witness done and we don't then have to
16 replay a second video.

17 CHIEF JUDGE BUMB: That's how it's going to go. And
18 that time will count towards your time. And the jury will be
19 instructed that this is now part of the defendant's case.

20 MS. LOCKARD: Thank you.

21 MR. SLATER: I'm not sure what -- I think there was a
22 little nuance there.

23 CHIEF JUDGE BUMB: If you're going to call Mr. Smith,
24 okay, and you're going to play Mr. Smith's video deposition
25 testimony by -- this is how I've done it in other cases. If

1 you're going to play the videotape testimony of Mr. Smith,
2 you're going to play it; then if the defendants want to then
3 play their affirmative part of the case of Mr. Smith, they're
4 going to hear Mr. Smith right then and there.

5 Sometimes the way I've done it is that, because the
6 jury follows along, sometimes the way I've done it is
7 everything that he says that's plaintiff's part of the case is
8 in yellow. If it's defendant's part of the case, it's in
9 purple so that the jury can then know, and then when they go
10 back and review the testimony, they have the transcripts, even
11 though they have to rely upon the video itself as the evidence.
12 That has worked very effectively, I think, in some of my cases,
13 because then it's just Mr. Smith testifying and it's not this
14 up and down and now we're going to play him again and they're
15 like didn't we just hear from him like two weeks ago. It's so
16 much more helpful to the jury. And so -- but that time gets
17 allocated to each party.

18 MR. SLATER: My experience is this, and I've done it
19 with some of the lawyers here and tried cases to conclusion,
20 first of all, we think it's very prejudicial because our
21 designations are done where we focus on what we want to ask
22 about, and then the defense would like to put in their
23 testimony because then it mixes in and the jury loses the flow
24 because they don't know what we're actually trying to impart to
25 them. That's what happens.

1 What you do find out is this, again, my experience
2 and it's rock solid experience with some counsel here, and I
3 don't blame them for doing it, we go to trial, we're at this
4 stage and the defense says we got all this video we want to
5 play at the same time the plaintiffs play theirs, and the judge
6 in some cases that I'm thinking of said no, these are trials
7 that we had in New Jersey, said no, this is the most recent
8 examples, said the plaintiff has the right to play their
9 designations and then I will tell the jury at that time look,
10 the defense has a case also. In their case they have the right
11 to play other testimony from their witness, so don't make any
12 final decisions on this witness, leave a space in your notes,
13 and then in their case they can play the video they want to
14 play. And what always happens is however much time they said
15 they really wanted to play in our case, when they actually do
16 it in their case, when it's not going to completely disrupt the
17 flow of our case, goes down to this, goes down much smaller,
18 because there was never an intent to actually put those
19 witnesses in the case unless it was going to be injected into
20 our case and destroy our ability to give a coherent and focused
21 presentation of our case, which we have the right to put on.

22 So I would suggest that, for example, I would suggest
23 that Your Honor at least think about that or give us a little
24 time to go back and forth and see how long the videos are that
25 we have and see what it really looks like.

1 CHIEF JUDGE BUMB: There has to be so many witnesses
2 that it's just not that big of a deal. And just out of
3 fairness to the jury, just one time play the video and then,
4 you know, maybe there's certain witnesses you'll persuade me,
5 Judge, don't do that because it's too prejudicial because their
6 part of the case goes two hours and mine only goes five
7 minutes, fine. You might persuade me. But there should be --
8 most witnesses should only be played once and not this back and
9 forth.

10 I mean, I get it. But if the witness were live, then
11 the defendants would cross-examine that witness and get their
12 case out.

13 MR. SLATER: Ah. Ah. But if we put the witness on
14 live and let's say that the witness is relevant to four or five
15 different topics, but we say, you know what, we're just putting
16 this witness on, we're going to only question on these two
17 areas because that's the part that we want to put in our case
18 and we don't want to go into these two other areas where the
19 cross is going to let them put their entire trial theme in and
20 their whole case and just lay it all out. So we said we're
21 just going to make a strategic decision to limit it to this.

22 If the defense is allowed after we do that, because
23 normally they would be limited to the scope of direct, and then
24 they have the right in their case if they want to do their own
25 thing. And that's what usually has happened in my trials, they

1 then could put the witness on in their case, and the Judge
2 instructs the jury and says, look, they both have a case,
3 certain witnesses may appear more than once.

4 And, again, what you always find is there's this huge
5 need for them to get this testimony in until then they have to
6 do it in their case and then they don't play, because it
7 doesn't really do anything substantively helpful other than
8 completely obscure the important admissions that we obtain that
9 we're trying to present to the jury and it's enormously
10 prejudicial, whereas -- I understand what you're saying, but
11 maybe just have an open mind to the idea that if you tell the
12 jury, look, this witness is going to be played for 20 minutes,
13 the defense has the right to bring that witness back, so
14 understand that's not the end of the story and just keep your
15 notes set, you'll see that witness again and then you could put
16 it together, usually the witness never comes back anyway.

17 CHIEF JUDGE BUMB: Let me see what it all looks like
18 when you folks are mapping it out.

19 MR. SLATER: Thank you. And we'll start to talk, I
20 think.

21 CHIEF JUDGE BUMB: Probably comes under the category
22 of we're talking about one or two witnesses, so let's just see
23 what it looks like when you all map it out.

24 MR. SLATER: Probably.

25 CHIEF JUDGE BUMB: Uh-huh.

1 MR. SLATER: And we can commit to start to talk -- I
2 mean, like, I have a list. I actually can tell you right now,
3 our trial team spent about three or four hours the other day,
4 went through every witness in the case, and we put it all
5 together, and we're right now at about 75 hours to put -- and
6 That's assuming cross-examination, all the things with the
7 defense is going to want to do also.

8 Because, for example, like Dr. Hecht, we've allocated
9 a day for him. We assume he'll go on the stand, the direct
10 will be around two hours or so, and then the defense will cross
11 and hopefully we get him done in a day.

12 MS. ALLON: So your 75 hours is for both sides?

13 MR. SLATER: No. It's for our case. Remember, we're
14 trying a case against three multi-national corporations. We
15 have to make the case against ZHP. We have to make the case
16 against Teva. We have to make the case against Torrent. If we
17 were just trying the case against ZHP, four weeks we could do
18 it, we'd get it done. But we have to also put on the Teva
19 case, the Torrent case.

20 CHIEF JUDGE BUMB: I thought you told me that this
21 was a four- or five-week trial.

22 MR. SLATER: I never said that, except when Judge
23 Kugler spoke to us and said how long could it be done, he said
24 I want to get it done in four weeks, and I said I don't know if
25 we can do that. We can do it if you rule certain ways on

1 certain motions. Like if he ruled for us on summary judgment
2 that the drugs were adulterated as a matter of law because cGMP
3 violations were committed as a matter of law --

4 CHIEF JUDGE BUMB: Let me just see, map it all out.
5 You folks map it all out and the witnesses. But I don't see
6 why this trial can't be done in four weeks.

7 MR. SLATER: Okay.

8 CHIEF JUDGE BUMB: It probably is overkill.

9 MR. SLATER: And we're sharpening our pencil every
10 day, I can promise you, cutting these down.

11 CHIEF JUDGE BUMB: I do not see this as a four- to
12 five-week trial; I just don't. I just don't.

13 MS. LOCKARD: And, Your Honor --

14 MR. SLATER: There's an easy way to do it. If you
15 just will revisit and grant us summary judgment on cGMP and
16 adulteration, four weeks is easy.

17 CHIEF JUDGE BUMB: No. If you folks would go talk
18 settlement, that would even be easier.

19 MR. SLATER: I'm here ready to talk.

20 MS. ALLON: So, Your Honor, I just want to be clear
21 because I think all of us would prefer not to live with an
22 overhang of uncertainty about this trial. So if the mandate is
23 the Court thinks we can do it in X amount of time, the parties
24 should go negotiate how that time is going to be divided.

25 CHIEF JUDGE BUMB: Yeah. I mean --

1 MS. ALLON: Is that the best --

2 CHIEF JUDGE BUMB: You're going to work -- if you
3 work till midnight tonight and present something to me in the
4 morning, even better. You're going to present a map to me.
5 I'm going to look at it with Judge Vanaskie. He has a much
6 better handle on the players. And if I look and see that this
7 looks reasonable or looks unreasonable, and if I say it looks
8 reasonable, but it's a ten-week trial, then we're going to try
9 it in the summer. I don't know what else to say.

10 MR. SLATER: We'll work hard with the defense to try
11 to work it out, because we're not sure how long they need to
12 try their case also.

13 CHIEF JUDGE BUMB: Yeah. So you'll sit down and try
14 to map it all out.

15 MR. SLATER: Fair enough.

16 MS. ALLON: We have been crystal clear about how long
17 we need. 80 hours for this trial. We think it can be done.
18 We think the time should be split 50/50. So we can present
19 this case in 40 hours. We've said that to Judge Kugler. We've
20 said that to this Court. Our position has never changed on
21 that topic.

22 CHIEF JUDGE BUMB: And I want to see why that can't
23 be the case. Let's see.

24 MR. SLATER: Okay. Thank you very much.

25 MS. ALLON: Thank you, Your Honor.

1 MS. ROSE: Your Honor, can I ask for a clarification
2 on one issue related to the deposition designations?

3 CHIEF JUDGE BUMB: Yeah.

4 MS. ROSE: Mr. Slater made a number of
5 representations about deposition designations and what
6 witnesses have said, and I just wanted to clarify, he made a
7 comment saying that we could take -- he could take his
8 deposition designations for, for example, I believe there's 15
9 ZHP witnesses that he could take those deposition designations
10 and take a couple of them to Judge Vanaskie to present
11 objections and then apply them to the rest of the depositions.
12 I fundamentally disagree with that, because a lot of our
13 objections are based on plaintiffs' very carefully selecting
14 portions of a witness's answer that it's a very individualized
15 circumstance. So you can't -- even if Judge Vanaskie finds in
16 this particular circumstance the rest of the answer was
17 nonresponsive, that's not necessarily the case with respect to
18 every witness. And I'm concerned about getting into a
19 situation where now if they are presenting deposition clips
20 from witnesses that we've offered to bring live, that then if
21 he's going to get, you know, a ruling from Judge Vanaskie on
22 maybe one or two witnesses and say that applies to everyone
23 else and then there will be very misleading testimony
24 presented.

25 CHIEF JUDGE BUMB: No. If you folks want to argue

1 about every sentence, then go for it.

2 MR. SLATER: I was not saying that, though. What I
3 was saying is as officers of the court, and at a level of trial
4 practice we're at, if we can't understand when Judge Vanaskie
5 makes a handful of rulings how that would likely apply to other
6 designations and work things out, then we shouldn't be doing
7 what we're doing. I wasn't saying they don't have a right to
8 object still, but I would think that we all take the guidance
9 and reduce the disputes down to really the ones that have to be
10 argued. I was not saying decide two and everything else is
11 done. I was not suggesting that.

12 MS. ROSE: I just want to make the point that I feel
13 that there are going to be more disagreements on deposition
14 designations. I know that --

15 CHIEF JUDGE BUMB: No.

16 MS. ROSE: I know that Your Honor very much did not
17 want that. We do not want that, but that is just the case.

18 CHIEF JUDGE BUMB: Well, you folks will keep plugging
19 along. And if you folks just can't get into an agreement,
20 then, you know, I don't know. We'll try the case next year.

21 MR. SLATER: I'm confident that we can present to
22 Your Honor something that you'll be able to look at and say
23 reasonably we could start November 4.

24 CHIEF JUDGE BUMB: Okay.

25 MR. SLATER: I think it's very likely that when the

1 rubber hits the road, it's going to need to go into December,
2 because the defense is also going to need enough time to put
3 their case on. But I have no doubt that we're going to be able
4 to present a reasonable trial to Your Honor, and you're going
5 to understand why we're saying how long it needs to take.

6 CHIEF JUDGE BUMB: When am I picking a jury?

7 MS. ALLON: The last week of October, Your Honor. I
8 think is what we had talked about.

9 MR. HONIK: The Wednesday before.

10 MR. SLATER: Yeah. I think you said October 30th.
11 31st.

12 MR. HONIK: 28th.

13 MR. SLATER: I assume no Halloween costumes allowed
14 during jury selection.

15 CHIEF JUDGE BUMB: No. Have you folks worked on the
16 questionnaire?

17 MR. SLATER: I can't hear you.

18 MS. LOCKARD: Yes, Your Honor. We have worked on it.
19 It has been submitted. It was attached as an exhibit to --

20 CHIEF JUDGE BUMB: I have it?

21 MS. LOCKARD: It is attached as an exhibit to
22 Mr. Slater's agenda submissions for this.

23 It was Exhibit --

24 MR. SLATER: Two?

25 Yeah. It's in here somewhere.

1 CHIEF JUDGE BUMB: So are there objections?

2 MS. LOCKARD: There are a few points of disagreement
3 that are mapped out in redline with notations.

4 MR. SLATER: Can I suggest, we probably don't need to
5 do that today.

6 CHIEF JUDGE BUMB: Well, when are we going to do it?

7 MR. SLATER: I just was -- it's a short thing. I was
8 just saying if Your Honor hadn't seen it yet, it's probably
9 something we could do either tomorrow or next week when we're
10 in court because it's getting late.

11 MS. LOCKARD: It is an exhibit to Mr. Slater's
12 submission.

13 CHIEF JUDGE BUMB: No. I have it here. I'm just
14 looking.

15 MS. LOCKARD: I think you could probably make rulings
16 without argument on those. They're very discreet.

17 CHIEF JUDGE BUMB: There's only one, right? Oh, no.

18 MR. SLATER: I think there's like five or six, right?
19 We did a good job of narrowing them down.

20 CHIEF JUDGE BUMB: It's so small, I have to put on my
21 glasses.

22 Do you have the claim in here?

23 MR. SLATER: Yes.

24 CHIEF JUDGE BUMB: That would be interesting to read
25 what you all are saying, because you couldn't agree on it this

1 morning.

2 MR. SLATER: Yeah. It's at the bottom of page 1,
3 Your Honor, the description of the case.

4 CHIEF JUDGE BUMB: Let's see, the plaintiff...
5 (Court reading.)

6 CHIEF JUDGE BUMB: Yeah. I can't rule on that until
7 I get that further briefing from you folks. That's what we
8 were discussing earlier. So I'll have to wait on that one.
9 Make a note.

10 I'm not going to -- I don't ask any such questions as
11 number 3 -- I mean 30. I won't ask them.

12 I won't ask 31. I don't. Well, I won't ask 32.

13 MS. LOCKARD: I'm sorry. I couldn't hear Your Honor.

14 CHIEF JUDGE BUMB: I will not ask 30, 31, 32, 33, or
15 34.

16 I don't find them to be probative.

17 If it's in pink, what does that mean; that there's an
18 objection by the plaintiff; is that -- am I right about that?
19 Mr. Slater.

20 MR. SLATER: You said A3, Your Honor?

21 CHIEF JUDGE BUMB: If it's in pink.

22 MR. SLATER: Oh. No. The pink describes both sides'
23 positions, Your Honor, because some of them the defense
24 proposed something, the plaintiffs object and they propose an
25 alternative.

1 CHIEF JUDGE BUMB: Oh, I see.

2 Okay. 40 I'm not going to ask. And 38 and 39 you
3 folks will have to come up with another question that somehow
4 elicits a bias. That's what you're looking for. But not in a
5 way that you're asking it.

6 I just find the questions to be inflammatory. "Do
7 you think a pharmaceutical company would misrepresent the
8 ingredients in their medication to make a profit?" Obviously
9 if someone answers yes, you've elicited the bias. But you're
10 going to -- it's just an inflammatory question. I want it to
11 be reworked.

12 MS. LOCKARD: For 38 and 39?

13 CHIEF JUDGE BUMB: Yes.

14 You can get to a bias in a different way, such as
15 generically do you have any opinions about pharmaceutical
16 companies that you think would, you know, you know, that the
17 Court should know or whatever. And you're probably going to
18 get things at sidebar which is they make too much money, that
19 kind of thing, okay. Is that going to be helpful? I don't
20 know. So you're going to have to come up with a -- whatever --
21 a better...

22 Same is true for 51.

23 I don't -- all of 51 I have a problem with.

24 MS. LOCKARD: So just for clarification.

25 CHIEF JUDGE BUMB: Yeah.

1 MS. LOCKARD: 51, the parties did not object to the
2 question itself.

3 CHIEF JUDGE BUMB: I know. But I don't like the
4 questions.

5 MS. LOCKARD: Understood. Okay.

6 CHIEF JUDGE BUMB: I just don't like the questions.

7 MS. LOCKARD: So we'll rework A, B and C at 51.

8 CHIEF JUDGE BUMB: Yeah.

9 Like, do you think any juror -- let's just, for
10 example, 51C, do you think any juror, any rational juror, would
11 say anything other than "agree strongly"?

12 I don't know. Same is true for 58 and 60.

13 MR. SLATER: Are you saying, Your Honor, 58, 59 and
14 60 are out or --

15 CHIEF JUDGE BUMB: No. I mean, I understand what
16 you're trying to get at.

17 MR. SLATER: Or rework them.

18 CHIEF JUDGE BUMB: I mean, I don't know. What do you
19 expect jurors to say?

20 MR. SLATER: Oh, they're not our -- the plaintiffs
21 are objecting to those questions.

22 CHIEF JUDGE BUMB: No, I know. But by the same
23 token, I mean, parties are entitled to ferret out biases. But
24 I just -- some of these questions are, you know, they're just
25 too inflammatory. I just -- I want -- I just tried a whole --

1 a criminal case, for example, and the defendants -- it was an
2 illegal immigration case, and the defendants wanted me to ask
3 all kinds of questions about our former president.

4 I mean they're just, you know. You can get to
5 positions that jurors might hold, but you don't have to ask
6 them an inflammatory question in a way. So propose something
7 alternative.

8 MS. LOCKARD: But Your Honor doesn't have an
9 objection to us seeking or asking questions seeking bias
10 related to Chinese, Israeli, or Indian companies?

11 CHIEF JUDGE BUMB: Yes. But I do have a problem with
12 ethics. I don't know what that means, about the ethics of
13 Chinese companies. I mean, I don't know that a juror is even
14 going to know what that means. It should be something more
15 like do you hold any strongly held beliefs about companies who
16 do business with the United States, including Chinese, Israeli
17 or Indian companies that might affect your ability to be fair
18 and impartial? And if they answer yes, then we'll go to
19 sidebar and figure out what that is.

20 Yeah.

21 Fifty-two is a question I always ask. I always ask
22 that. And it's an instruction I always give that they have to.

23 So 52 is fine.

24 MS. LOCKARD: I believe that's it, other than the
25 first --

1 CHIEF JUDGE BUMB: Okay. So try to rework those.
2 I'm glad I looked at them.

3 MR. SLATER: We'll get it done.

4 MS. LOCKARD: Okay.

5 CHIEF JUDGE BUMB: One of the other things, so I'm
6 going to have, our IT people are working on it, so all the
7 jurors will have iPads. So I don't know what that means in
8 terms of what you folks all have to do. But all of the
9 documents will be downloaded on their iPads, and I think that
10 will be very helpful. And then we have to figure out a way --
11 have any of you tried cases where the jurors have had iPads?

12 (No response.)

13 CHIEF JUDGE BUMB: No? All right. So then I'll have
14 to figure out and sort of explore all of the procedures with
15 you, like how we prevent them from looking forward to documents
16 that aren't -- I'll have to figure that out and I'll have to
17 talk to the IT people. I think that would be very helpful and
18 help streamline the case so it's not, you know, all the --
19 everything will be computerized. I think that will be very
20 helpful.

21 Sidebars I'm going to have -- you'll all have phones
22 at your desk as opposed to having 15 of you meet me over at
23 sidebar. I'll just hear you on the phone and there will be
24 white noise. The jury won't hear. So we can have a
25 conversation. You'll get my ruling. So that will go a little

1 quicker, too. And I'm trying to come up with some other ways
2 to kind of streamline it.

3 MR. SLATER: So we'll be sitting at counsel table
4 arguing the objections right from here?

5 CHIEF JUDGE BUMB: Yes, arguing here, yes. But the
6 jury won't hear it because they'll hear the white noise.

7 MR. SLATER: Never done that.

8 CHIEF JUDGE BUMB: Yeah. I think it will be more
9 effective.

10 MR. SLATER: Judge, can I ask a question about jury
11 selection?

12 CHIEF JUDGE BUMB: Yeah.

13 MR. SLATER: And I think the defense might have been
14 agreeable to this. When you're questioning the witnesses,
15 we're obviously going to have the questionnaires and we're
16 going to know which questions we think are important to
17 follow-up on and all, is it possible to question the jurors
18 when they actually have to -- when they have answers that we
19 need to talk about rather than in open court, either in the
20 jury room or somewhere else where we can bring the jurors in
21 one at a time? We find it's easier -- I found in some trials
22 it's easier for all the counsel to be able to interact.

23 I don't know if you let us ask questions also as
24 follow-up or if Your Honor does all the questioning. Those are
25 probably some of the nuances that I'm sure all the counsel are

1 questioning or wondering about. But we would certainly ask to
2 consider doing it so that the jurors come one at a time into
3 the room to the extent there needs to be follow-up.

4 CHIEF JUDGE BUMB: Well, the way I normally do it is
5 you're going to have these questionnaires.

6 They're going to get these ahead of time, right?

7 MS. LOCKARD: Yes.

8 CHIEF JUDGE BUMB: We're going to mail them to the
9 jurors; is that what we're doing? We're planning on mailing
10 them to the jurors?

11 MS. LOCKARD: That was our understanding.

12 MR. SLATER: We -- I thought they were going to
13 actually come to court to fill them out, so that --

14 MS. ALLON: No, no.

15 (Counsel conferring.)

16 (Discussion was held off the record in open court.)

17 MR. SLATER: Or electronically, yeah.

18 MS. ALLON: Our understanding from Judge Kugler was
19 that we'll get them ahead of time. They'll be sent to them.
20 They will fill them out. We'll get them. Because -- we talked
21 with Judge Kugler about this process.

22 MR. SLATER: No. Well, my --

23 CHIEF JUDGE BUMB: I think the better way to do it,
24 because it's such a -- it will be a long trial, and it's going
25 to be a lengthy questionnaire -- well, it's not --

1 MR. SLATER: We definitely need them in advance. Our
2 concern, which was discussed with Judge Kugler, was if you send
3 them to them at home, when they're filling them out, they can
4 sit there with their husband, wife, friends, fill it out.

5 CHIEF JUDGE BUMB: Yeah.

6 MR. SLATER: Perhaps not be as -- as opposed to if
7 they're here at the courthouse, they have to do it while
8 they're here. They have to answer based on their own
9 knowledge. They can't --

10 CHIEF JUDGE BUMB: Yeah; I'll do it the way I
11 normally do it. So the way I normally pick -- how many jurors
12 do you think we should pick?

13 MR. SLATER: I suppose it depends, but...

14 (Court conferring with deputy clerk.)

15 MR. SLATER: Your Honor, I thought that we were
16 originally going to have them come in and do it on the iPads
17 when they came to Court.

18 CHIEF JUDGE BUMB: Do it on the iPads?

19 MR. SLATER: That they would come in advance like of
20 the jury selection, have the questionnaires on an iPad or fill
21 it out in hard copy and then we can have them in advance. We
22 can make sure all the parties have them, and then we could look
23 at them for a day or two so that when we come into court, Your
24 Honor, for example, could say, look, this is Juror No. 12, you
25 have the questionnaires, do you have follow-up questions on any

1 of the answers? Do you have follow-up questions on any of the
2 answers? We could tell you what we have follow-up questions
3 on. Your Honor could decide -- then follow up and say you said
4 this, what did you mean by that, or you said you had this
5 opinion about pharma companies that are tremendously wonderful
6 or not tremendously wonderful, why do you say that or whatever.
7 But we'd be able to have that in advance so you don't have to
8 have us sitting here rifling through the questionnaires the day
9 of selection figuring out what we have. If we have it done in
10 advance for Your Honor's benefit, it will be much more
11 efficient because we're going to know what follow-up we want
12 with each juror at least based on their questionnaires.

13 CHIEF JUDGE BUMB: Well, let me think about it. But
14 let me tell you how I normally pick a jury, okay. So I just
15 have to figure out how many I am going to seat. So you
16 probably should think about that.

17 The way I normally do it is that the jurors fill out
18 the questionnaires. I bring them in, tell them about the case.
19 Give them a description of the case, tell them about the length
20 of the case and then have the parties introduce themselves, and
21 then they then recess and they go out and fill out the
22 questionnaires. And after they've filled out the
23 questionnaires, then the parties have an opportunity to review
24 the questionnaires, and then I have them come and they then
25 give their answers in open court as to their answers.

1 If there's any question that I feel that needs
2 follow-up, I will bring them to sidebar. But usually what I'll
3 do is I'll go through all -- let's just say I go through all 12
4 or 16, or how many I'm going to seat, there are some that
5 clearly don't qualify and I will strike them, sua sponte I will
6 strike them, and then usually it's the first, you know, 10 or
7 12, whatever we agree on, on struck jurors that sit as our
8 jury. If I have any follow-up questions, I come to sidebar.
9 And then you start exercising your peremptories once we have 20
10 qualified or whatever. I have to do the math. I haven't done
11 the math.

12 Does that make sense?

13 MR. SLATER: I think it does.

14 CHIEF JUDGE BUMB: I do pick my juries differently
15 than I think any other judge here.

16 MR. SLATER: Interesting. When you say you question
17 the jurors first, I assume you mean on their biographical,
18 their background?

19 CHIEF JUDGE BUMB: No.

20 MR. SLATER: You wouldn't be going through the
21 questionnaires, would you?

22 CHIEF JUDGE BUMB: Do you have that in here?

23 MR. SLATER: Because we don't have like the basic
24 what do you do for a living and all that I don't think.

25 CHIEF JUDGE BUMB: You don't? Yeah, you do.

1 MR. SLATER: Oh, we do in the beginning, you're
2 right.

3 CHIEF JUDGE BUMB: Yeah.

4 MR. SLATER: A little bit.

5 Would you be going through the whole questionnaire or
6 just the biographical background?

7 CHIEF JUDGE BUMB: No. I have them stand up and say:
8 My name is Renée Bumb, I'm female, my date of birth.

9 Why do you need the date of birth? Let's take that
10 out and just put year of birth. Let's change that. Well, why
11 do you even need that? It just says age. Take the date of
12 birth out.

13 MR. SLATER: That's fine.

14 CHIEF JUDGE BUMB: Where do you live, and then they
15 just give you their answers. A lot of times they'll just --
16 and then when they get to 8, they'll say yes. 9, no. 10, yes.
17 11, no. 12, yes. And then they just go through and give us
18 their answers.

19 MS. ALLON: So, Your Honor, I do actually agree with
20 Mr. Slater that in my experience --

21 CHIEF JUDGE BUMB: Yeah.

22 MS. ALLON: -- when the parties are able to get the
23 questionnaires before, it streamlines the selection.

24 CHIEF JUDGE BUMB: Yeah.

25 MS. ALLON: Because everybody decides where they may

1 have cause issues, and they can just figure that out in advance
2 rather than in the moment and it just shortens jury selection.

3 CHIEF JUDGE BUMB: Yeah.

4 MS. ALLON: So I don't know if it's possible to do.

5 CHIEF JUDGE BUMB: Yeah, I might do that just because
6 the questionnaires are long, and the length of -- you're going
7 to lose a lot of jurors who can't sit this long.

8 MS. ALLON: Right, exactly.

9 CHIEF JUDGE BUMB: But I guess I'll -- okay. Subject
10 to change, I'll bring them in, all of them, they'll all fill
11 out the questionnaires. I think we're going to have more than
12 75 come in.

13 How many jurors should we seat? So if we start with
14 the promise that we need -- how many jurors? We need six
15 jurors. I would say probably seat 12, don't you think?

16 MS. BROWN: Yes.

17 MS. ALLON: Yeah. I think for a trial of this
18 length, 12 makes sense.

19 CHIEF JUDGE BUMB: Seat 12.

20 I'm just trying to do the math how many I have to
21 prequalify. How many peremptories? You'd think I would know
22 this. Nine, 12. So 12 peremptories.

23 MR. SLATER: Your Honor, 12 with the intent to have
24 six deliberate; is that what you said?

25 MS. ALLON: No, no. Our view would be -- oh, sorry.

1 I don't know if you agree, but my view is that anybody who sits
2 should deliberate.

3 CHIEF JUDGE BUMB: Well, if we seat 12, then all 12
4 have to deliberate unless there's an agreement otherwise,
5 although seating 12 maybe -- yeah.

6 MR. SLATER: I don't think we need 12. I would think
7 if we -- you need six for a valid verdict, right?

8 MS. BROWN: Right.

9 MR. SLATER: So, I mean, I would think that 10 would
10 probably be sufficient.

11 CHIEF JUDGE BUMB: Ten.

12 MS. BROWN: And, Your Honor, just given the length we
13 would ask to seat 12. I just tried a six-week case in the
14 District of New Jersey and we lost three jurors over that time
15 period.

16 CHIEF JUDGE BUMB: Criminal or civil?

17 MS. BROWN: Civil, yes.

18 CHIEF JUDGE BUMB: Okay.

19 Well, let me think about it. No less than 10. Maybe
20 12. So let's just say if we seat 12, and we have 12
21 peremptories, how many do I have? I'm just trying to do the
22 math, which I'm not very good at.

23 So I have to have 24 prequalified, right? Am I doing
24 the math right?

25 MS. ALLON: But, Your Honor, I seem to recall a

1 submission when we talked about the number of peremptories --

2 MR. SLATER: Yeah. It was agreed that we would have
3 the same number as the defendants.

4 MS. ALLON: I thought we agreed to three and three.
5 It wasn't going to go per defendant.

6 MR. SLATER: Right. It was an equal number. I don't
7 remember what the number was, but it was equal.

8 MS. ALLON: It definitely wasn't 12.

9 CHIEF JUDGE BUMB: Well, that's better.

10 MS. ALLON: Yeah. So that makes it faster.

11 MR. SLATER: Whatever we have, you guys have the same
12 total.

13 MS. ALLON: We have the same, correct.

14 CHIEF JUDGE BUMB: Okay. All right. So then we have
15 to prequalify approximately if there's only six peremptories,
16 then I have to prequalify 18 jurors, if we seat 12, okay.

17 It's doable.

18 Jurors love to serve. That's my theme.

19 Okay. All right. So can I be of help on anything
20 else? Anything I didn't resolve?

21 (No response.)

22 CHIEF JUDGE BUMB: I really am anxious to get that
23 briefing.

24 MS. ALLON: Yes.

25 CHIEF JUDGE BUMB: Because I really want to get a

1 handle on this.

2 MS. BROWN: And, Your Honor --

3 CHIEF JUDGE BUMB: And I think a lot is going to
4 depend upon what the plaintiffs tell me the warranty is that
5 was breached. Yeah. Okay.

6 MS. BROWN: And, Your Honor, just to ask for
7 clarification, I'm -- so I have a December 3rd trial in front
8 of Judge Shipp in the District of New Jersey. As I understood
9 the Court to be saying, tonight we sit down, hammer out what
10 four weeks looks like with an equal split and we report to Your
11 Honor in the morning.

12 CHIEF JUDGE BUMB: Yeah.

13 MS. BROWN: Okay.

14 CHIEF JUDGE BUMB: What kind of case is it before
15 Judge Shipp?

16 MS. BROWN: It's the talc MDL bellwether trial, Your
17 Honor. And I represent Johnson & Johnson.

18 MR. SLATER: I didn't realize we were supposed to
19 have this done by tomorrow morning the entire -- we're going to
20 now talk through the entire --

21 CHIEF JUDGE BUMB: Didn't I say you're just going to
22 go out and talk, go use my jury room.

23 MR. SLATER: Okay. All right. Then we'll do it.

24 CHIEF JUDGE BUMB: Use my jury room.

25 MR. SLATER: We'll go in.

1 MS. BROWN: I think we have to, Your Honor, because
2 that's an enormous uncertainty. This bellwether has been
3 pending. We had a Daubert hearing in 2019. This case is going
4 to try now for the first time. I mean, if what we're looking
5 at is even the possibility that I wouldn't be able to try that
6 on December 3rd, that creates enormous problems for my client,
7 my clients, and I know the same is true for my codefendants.
8 So I just -- I would be --

9 CHIEF JUDGE BUMB: So I have a solution. Off the
10 record.

11 (Discussion was held off the record in open court.)

12 (Counsel conferring.)

13 CHIEF JUDGE BUMB: We're off the record.

14 (Discussion was held off the record in open court.)

15 CHIEF JUDGE BUMB: Anything else I can do for you
16 all?

17 MS. ROSE: Your Honor, can I raise one more issue? I
18 don't know if you want to go back on the record.

19 CHIEF JUDGE BUMB: Yes, let's go back on the record.

20 MS. ROSE: I just have one issue on the briefing
21 you'd like.

22 CHIEF JUDGE BUMB: Yeah.

23 MS. ROSE: I think it makes sense because it sounds
24 like, especially on the first issue, is plaintiffs' warranty
25 claim, what their theory is, and then to proffer case law on

1 whether or not their theory of adulteration retroactively means
2 no value. It probably makes sense for plaintiffs to submit the
3 initial brief and then for defendants to respond. We have a
4 lot of issues for us to discuss and to work out between us. So
5 I didn't -- I wanted to have some clarity on what it is --

6 CHIEF JUDGE BUMB: It comes down to what is the
7 warranty that -- what is the warranty or warranties that were
8 communicated to the TPPs and how were those warranties
9 breached. So that's the first question, right? Because it
10 does matter, we're talking about TPPs, we're not talking about
11 consumers. We're not talking about, you know, prescribing
12 physicians, so...

13 MR. SLATER: Understood.

14 CHIEF JUDGE BUMB: That makes a difference. And
15 there is this, it appears, this disconnect about even that from
16 this morning.

17 MR. SLATER: Which is -- oh, I'm sorry.

18 CHIEF JUDGE BUMB: Which the second issue is,
19 assuming that that breach, that the plaintiffs prove that there
20 was a breach of that warranty, does that mean that you get the
21 full refund that you say you get?

22 There's also that disconnect. The parties have
23 spoken about benefit-of-the-bargain. The parties have spoken
24 about strict liability. The parties have spoken about, you
25 know, I don't remember what it's called, the quantity --

1 MS. ALLON: Quantity effects.

2 CHIEF JUDGE BUMB: Yes, that.

3 And so it's very intriguing to me. And now I'm
4 sitting up here saying, hmm, maybe I'll just hold off and force
5 you folks to settle this because you are not going to know how
6 I'll rule, but -- or maybe I'll rule and it helps settlement.
7 So that's all gone into my calculation now, too.

8 But at the end of the day, though, is I need to have
9 clarity about what the claim is and where is the case law that
10 supports the plaintiffs' position, and then the defendants,
11 where is the defendants' position as to what supports.

12 So I want simultaneous briefing on the issue of the
13 damages, because let's both assume on the issue of briefing
14 plaintiffs have shown a breach. Let's assume that, okay. So
15 that you don't need to wait to hear from them on what their
16 warranty claim is. I just need clarity on that, too. What's
17 the damages? And what is the -- what are the parties permitted
18 to introduce with respect to damages?

19 MR. SLATER: And I think you're going to see, Your
20 Honor, also, as far as the warranties, I believe Judge Kugler
21 ruled that there's actually, as a matter of law, that the very
22 saying, I think I'm paraphrasing, that by the defendants saying
23 this is valsartan USP, Orange Book rated, that was the
24 warranty, and as a matter of law held that that was the
25 warranty by holding it out to the world that way.

1 CHIEF JUDGE BUMB: Well, show it to me and prove it
2 to me.

3 MR. SLATER: No, obviously, I understand. I just
4 want to say I think that --

5 CHIEF JUDGE BUMB: Because they're saying with
6 respect to the TPPs that's not what the warranty is.

7 So lay it out to me, show me where that's been in the
8 complaint.

9 MR. SLATER: Will do.

10 CHIEF JUDGE BUMB: I'm just going to throw another
11 hypothetical out.

12 I mean, it just seems to me that there's got to be
13 case law out there that helps me. So what about all the
14 salmonella cases for people who don't get sick but ate it
15 anyway?

16 MR. SLATER: We'd have to look. I think it's going
17 to ultimately be straightforward warranty law, frankly, on the
18 warranty claim.

19 CHIEF JUDGE BUMB: I don't know.

20 MS. ALLON: It's --

21 CHIEF JUDGE BUMB: I don't know. It's intriguing to
22 me that I'm struggling. Maybe you all aren't, but I am, I'm
23 struggling with it. It's interesting to me.

24 Anyway. Good to see you all. I'll see you at 9:30
25 tomorrow, okay.

1 Have a good night. Thank you.

2 MS. ALLON: Thank you, Your Honor.

3 THE COURTROOM DEPUTY: All rise.

4 (Proceedings concluded at 4:55 p.m.)

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6 **FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**
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8 I certify that the foregoing is a correct transcript
9 from the record of proceedings in the above-entitled matter.

10
11 /S/John J. Kurz, RDR-RMR-CRR-CRC

September 11, 2024

12 Court Reporter/Transcriber
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